

Exhibit A

Part 2 of 3

Schondelmeyer, Pharm.D., Ph.D., Stephen W. - Vol. II

Washington, DC

February 26, 2009

Page 374

UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MASSACHUSETTS

IN RE: PHARMACEUTICAL) MDL NO. 1456
INDUSTRY AVERAGE WHOLESALE) CIVIL ACTION
PRICE LITIGATION) 01-CV-12257-PBS
THIS DOCUMENT RELATES TO)
U.S. ex rel. Ven-a-Care of) Judge Patti B. Saris
the Florida Keys, Inc.)
v.) Chief Magistrate
Abbott Laboratories, Inc.,) Judge Marianne B.
No. 06-CV-11337-PBS) Bowler

Videotaped deposition of STEPHEN W.

SCHONDELMAYER, PHARM.D., PH.D.

Volume II

Washington, D.C.

Thursday, February 26, 2009

9:00 a.m.

Schondelmeyer, Pharm.D., Ph.D., Stephen W. - Vol. II

February 26, 2009

Washington, DC

<p style="text-align: right;">Page 399</p> <p>1 actual acquisition cost, their actual cost of 2 dispensing and their typical net profit that's what 3 the state of California expects the pharmacy to submit 4 to them. 5 Q. I'll ask the same question you asked in 6 your report and for which you gave a one word answer 7 in your report. "Does this mean the pharmacy 8 overcharged on the generic prescription"? 9 A. And the answer is if all the assumptions 10 are met that these are their actual costs in all 11 cases, no. 12 Q. Thank you. If Medi-Cal or any Medicaid 13 program paid that pharmacy \$12.91 in reimbursement 14 would you agree with me that the Medicaid program did 15 not overpay that pharmacy? 16 MS. BROOKER: Objection, form. 17 A. Well, again, this would probably have been 18 subjected also -- since this is generic we're talking 19 about -- subjected to the lower of the estimated 20 acquisition cost plus the dispensing fee that the 21 state charged. And this would have been reduced. 22 Actually, Medi-Cal would have reduced this and the</p>	<p style="text-align: right;">Page 401</p> <p>1 would pay if that's what it said. 2 Q. I'm asking you whether the state should pay 3 as a matter of good public policy \$8.52 in the example 4 that we just gave? 5 MR. BREEN: Objection, form. 6 MS. BROOKER: Objection, form. 7 A. I can't answer that because the state has 8 to make their choices and they've made choices. 9 That's what their regulation is. They don't have the 10 option to pay 7.52 or whatever you're describing. The 11 formula is fixed, is known. The pharmacy would know 12 that up front too. And then the pharmacy's choice is 13 am I going to continue filling those prescriptions at 14 that price or am I not. 15 Q. If the pharmacy were paid \$8.52 for this 16 \$12.91 charge can you predict whether the pharmacy 17 would continue to participate in Medi-Cal? 18 A. I mean, this is -- first of all, it's a 19 hypothetical. This is one example. This is a 20 generic. The pharmacy would have to decide how much 21 that will affect their bottom line and how many 22 patients they have on this or similarly situated</p>
<p style="text-align: right;">Page 400</p> <p>1 pharmacy wouldn't have been paid 12.91. 2 The pharmacy would have submitted what they 3 were asked to by the state -- that is, their usual and 4 customary charge, which is 12.91 -- but the formula at 5 Medi-Cal would have looked at estimated acquisition 6 cost plus a dispensing fee of 7.25. It would have 7 looked at a maximum allowable ingredient cost if the 8 state had one. It would have looked at a federal 9 upper limit if it had one and added a dispensing fee 10 to each of those. And it would have compared to the 11 usual and customary charge of the 12.91. 12 Since the state pays a dispensing fee 13 that's less than the pharmacy's actual cost here, they 14 may have reduced the payment to the pharmacy. 15 Q. Would that be appropriate? 16 MS. BROOKER: Objection, form. 17 A. It's not a matter of if it's appropriate. 18 That's what the regulation is. 19 Q. Are you telling me that the state should 20 pay the pharmacy in our hypothetical \$8.52? 21 MS. BROOKER: Objection, form. 22 A. I'm telling you that's what their formula</p>	<p style="text-align: right;">Page 402</p> <p>1 generics and what the effect -- generics in general 2 are about 50 to 60 percent of the prescriptions but 3 they account for less than 20 percent of the dollars 4 in most cases in the pharmaceutical marketplace 5 because they're generally priced much lower. 6 The pharmacy would have to decide. Some 7 may continue to do so. As I described in that 8 California report at the end, I described that some 9 pharmacies will continue filling prescriptions even at 10 below cost because discontinuing them means they go 11 out of business quicker than if they slowly bleed to 12 death by taking low cost prescriptions over time. So 13 it depends on the pharmacy and how they're situated 14 financially and other issues that they need to 15 consider. 16 Q. You weren't asked to consider such an 17 analysis in this case with respect to the government's 18 retroactive reduction in ingredient cost payments, 19 were you? 20 MS. BROOKER: Objection, form. 21 A. No, I was not. 22 Q. Dr. Duggan, I'm going to hand you Exhibit</p>

8 (Pages 399 to 402)

Schondelmeyer, Pharm.D., Ph.D., Stephen W. - Vol. II

February 26, 2009

Washington, DC

<p style="text-align: right;">Page 403</p> <p>1 1093.</p> <p>2 A. Excuse me. I'm Dr. Schondelmeyer.</p> <p>3 Q. You'll understand my problem. Dr.</p> <p>4 Schondelmeyer, we're going to hand you Exhibit 1093</p> <p>5 which is Dr. Duggan's expert report in this case. I</p> <p>6 understand that you've reviewed this report in the</p> <p>7 past?</p> <p>8 A. I did look through it. I did not pore</p> <p>9 through it in detail.</p> <p>10 Q. You understand that Dr. Duggan calculated</p> <p>11 the difference between what Medicaid did pay for</p> <p>12 certain prescription drugs involved in this case and</p> <p>13 what Medicaid would have paid given certain</p> <p>14 alternative AWP's that he calculated based upon</p> <p>15 Abbott's average sales prices. Is that an accurate</p> <p>16 summary of what Dr. Duggan did?</p> <p>17 MS. BROOKER: Objection, form.</p> <p>18 A. I'm not sure that's not a complete summary.</p> <p>19 Those elements sound approximately close. But I'm</p> <p>20 sure there are more qualifications that he placed on</p> <p>21 it.</p> <p>22 Q. If you could turn to page 77 of Exhibit</p>	<p style="text-align: right;">Page 405</p> <p>1 report.</p> <p>2 Q. And that is a reduction in the prior</p> <p>3 sentence from \$109.444 million paid lowered by</p> <p>4 \$81.222 million paid, right?</p> <p>5 MS. BROOKER: Objection, form.</p> <p>6 A. I see the numbers and the results here.</p> <p>7 Again, I don't recall the details of the method of how</p> <p>8 he got there.</p> <p>9 Q. And then if you turn to page 80 of the</p> <p>10 report the bottom paragraph on page 80, the second</p> <p>11 sentence reads "This represents 68.3 percent of the</p> <p>12 \$47.702 million in Medicaid spending on complaint</p> <p>13 products." And do you understand there that for the</p> <p>14 remaining 38 states that Dr. Duggan analyzed that he</p> <p>15 calculated a difference, a reduction, of 68.3 percent</p> <p>16 from what Medicaid actually spent on those drugs</p> <p>17 between 1991 and 2001?</p> <p>18 MS. BROOKER: Objection, form.</p> <p>19 A. I see the numbers in the statements here.</p> <p>20 Again, I don't recall the details of the methods</p> <p>21 behind how he derived that.</p> <p>22 Q. And so that we are talking just in round</p>
<p style="text-align: right;">Page 404</p> <p>1 1093 if you look at the top paragraph of page 77 it's</p> <p>2 a half of a paragraph. This is in a section entitled</p> <p>3 "Medicaid summary for the first 12 states." And if</p> <p>4 you look at the last sentence it states "This value of</p> <p>5 difference is 74.2 percent of total Medicaid</p> <p>6 spending." Do you see that?</p> <p>7 A. I see that statement.</p> <p>8 Q. Do you understand that for the first 12</p> <p>9 states that Dr. Duggan analyzed he calculated a</p> <p>10 reduced total Medicaid spending of 74.2 percent given</p> <p>11 his analysis and the assumptions that he made?</p> <p>12 MS. BROOKER: Objection, form.</p> <p>13 A. I have not reviewed this in detail recently</p> <p>14 enough to recall all the aspects. So I could take</p> <p>15 your representation. But I wouldn't say that I agree</p> <p>16 with that. I could take it as an assumption.</p> <p>17 Q. You'll agree with me that Dr. Duggan's</p> <p>18 report says that he has calculated a difference of</p> <p>19 74.2 percent of total Medicaid spending, right?</p> <p>20 A. Yes, I agree that that statement is there.</p> <p>21 I didn't agree that I understand exactly how he got</p> <p>22 there because I don't recall all the details of the</p>	<p style="text-align: right;">Page 406</p> <p>1 numbers, I'll refer to Dr. Duggan's reduction --</p> <p>2 because I don't believe he calculates a percentage for</p> <p>3 the total of all states, all 52 states or 52 programs,</p> <p>4 I'll refer to that generally as a reduction of 68</p> <p>5 percent to be conservative in total Medicaid spending</p> <p>6 as a result of Dr. Duggan's calculations.</p> <p>7 MR. BREEN: Objection, form.</p> <p>8 A. I'd rather not use an inaccurate number.</p> <p>9 Q. All right. Have you been asked to analyze</p> <p>10 what the impact on providers and beneficiaries would</p> <p>11 be of a reduction of 68 to 74 percent in total</p> <p>12 Medicaid spending for the prescription drugs involved</p> <p>13 in this case?</p> <p>14 MS. BROOKER: Objection, form.</p> <p>15 A. I have not been asked to analyze Dr.</p> <p>16 Duggan's report or the results of that report.</p> <p>17 Q. Let me ask you based upon your expertise</p> <p>18 and the work you've done for pharmacies, would it be</p> <p>19 appropriate for a Medicaid program to reduce spending</p> <p>20 on pharmaceutical products by 68 to 74 percent without</p> <p>21 considering the impact on providers and beneficiaries?</p> <p>22 MS. BROOKER: Objection, form.</p>

9 (Pages 403 to 406)

Schondelmeyer, Pharm.D., Ph.D., Stephen W. - Vol. II

February 26, 2009

Washington, DC

<p style="text-align: right;">Page 407</p> <p>1 A. I think that would be a consideration that 2 the Medicaid program would take into account. They 3 may determine that there's no effect or that the 4 effect might play out in different places. Again, 5 they may determine that pharmacies have other generics 6 that are even lower cost than the ones used and these 7 might be very conservative estimates of the savings 8 rather than the full amount of savings. 9 Q. We're here talking about -- but I'm asking 10 about the impact on providers and beneficiaries of 11 reductions in payments to pharmacies of between 68 and 12 74 percent. Do you understand? 13 MS. BROOKER: Objection, form. 14 A. I understand. And I'm describing that 15 given a change -- I can't fully analyze it without 16 time and going through Dr. Duggan's report and other 17 factors. But pharmacies given a change may choose a 18 different generic product that costs less or that has 19 a more favorable payment to them. 20 Q. I'm not asking you to analyze it. I'm 21 asking you whether it would be appropriate for a 22 Medicaid program to reduce payments to pharmacies by</p>	<p style="text-align: right;">Page 409</p> <p>1 MR. BREEN: Objection, form. And that's an 2 improper question. 3 A. I can't answer that as asked. What I can 4 answer is that it would be appropriate for the state 5 to implement the policies and statutes and regulations 6 that exist, as exist in the Medicaid program. Then if 7 others, if providers, if beneficiaries, others, have a 8 disagreement with that they can take it up with either 9 the legislature or with the courts. 10 Q. So you're saying that it would not be 11 appropriate simply to reduce the payments by 68 to 74 12 percent without determining whether that has an impact 13 on access to care? 14 MS. BROOKER: Objection, form. 15 A. I'm saying that the percent reduction has 16 nothing to do with -- the state is obligated to follow 17 the program policies and to pursue what they think the 18 statutes and policies are, as they did in this case 19 and I believe they did in the California case that I 20 dealt in. The action then of providers and 21 beneficiaries is to take it up with the courts if they 22 disagree and the courts will determine what's</p>
<p style="text-align: right;">Page 408</p> <p>1 68 to 74 percent without conducting such an analysis 2 of the impact on providers and beneficiaries. 3 MR. BREEN: Objection, form. 4 A. If the change they're undertaking is what 5 they feel that the program statutes and regulations 6 and policies are expected, I think they would do that. 7 I think they would monitor to see what the effect is 8 and may take other consequential actions at a later 9 point in time. But -- 10 Q. I want to be very clear so that your 11 pharmacy clients in California if they see this 12 videotape will understand. 13 MS. BROOKER: Objection. 14 Q. It's your testimony that it would be -- 15 MR. BREEN: Objection, form. 16 Q. It's your testimony that it would be 17 entirely appropriate for the state of California to 18 reduce Medi-Cal payments for injection pharmaceuticals 19 by 68 to 74 percent without also considering the 20 impact on providers and beneficiaries. Is that your 21 testimony? 22 MS. BROOKER: Objection, form.</p>	<p style="text-align: right;">Page 410</p> <p>1 appropriate. 2 Q. Do the statutes and regulations include an 3 obligation to provide access to care to beneficiaries? 4 MS. BROOKER: Objection, form. 5 A. They do. But that's a different 6 perspective and the state can decide whether or not 7 they think there's an impact and then they can deal 8 with that. If others disagree, they can, again, take 9 it up with the courts or -- by taking action -- or 10 with the legislature. 11 Q. So it sounds like we're in agreement. You 12 would agree with me that simply reducing payments by 13 68 to 74 percent without considering access to care 14 and other regulatory requirements would be 15 inappropriate, right? 16 MS. BROOKER: Objection, form. 17 A. No, I did not say that. 18 Q. All right. 19 A. I will not agree to anything that describes 20 a percent reduction. I will agree that the state can 21 follow what they feel the statutes and regulations are 22 and their obligations in implementing the program and</p>

10 (Pages 407 to 410)

Schondelmeyer, Pharm.D., Ph.D., Stephen W. - Vol. II

February 26, 2009

Washington, DC

<p style="text-align: right;">Page 455</p> <p>1 Q. It's a joint engagement?</p> <p>2 A. That's my understanding. I'm not sure of</p> <p>3 the engagements, but --</p> <p>4 Q. You're not sure of your own arrangements</p> <p>5 with them?</p> <p>6 A. I send a bill to both.</p> <p>7 Q. Okay.</p> <p>8 A. They decide how they're going to pay it.</p> <p>9 That's not my concern.</p> <p>10 Q. Is there a written engagement letter</p> <p>11 between you and either Ms. Brooker or Mr. Breen that</p> <p>12 describes what your task in this case is going to be?</p> <p>13 A. I don't recall an engagement letter. There</p> <p>14 is -- the Department of Justice does have a form they</p> <p>15 do to authorize a certain amount of payment for</p> <p>16 experts and there is a contractual form. But beyond</p> <p>17 that I don't recall an engagement letter.</p> <p>18 Q. Did you do that in this case? Is that</p> <p>19 something you execute?</p> <p>20 A. No. The government executes and asked asks</p> <p>21 me to review and sign it. So I return it to them.</p> <p>22 Q. Did you do such a form for your Dey and</p>	<p style="text-align: right;">Page 457</p> <p>1 and Ms. Brooker what you were asked to do. If you</p> <p>2 can't answer that you can say I can't answer that or I</p> <p>3 don't remember. That's fine.</p> <p>4 A. I can answer that by referring to what I</p> <p>5 say -- I define in my report the scope of what I've</p> <p>6 been asked to address. And I'd like to be as accurate</p> <p>7 as possible and use that report.</p> <p>8 Q. My question is can you tell me as you sit</p> <p>9 here today --</p> <p>10 MR. MERKL: Are you going to tell him to</p> <p>11 put the report down and answer the question the way</p> <p>12 I've asked it?</p> <p>13 MS. BROOKER: I think he has answered the</p> <p>14 question. If you want to move on to another area you</p> <p>15 can or you can ask him to refer specifically to his</p> <p>16 report. It's up to you.</p> <p>17 BY MR. MERKL:</p> <p>18 Q. Can you without referring to your report</p> <p>19 tell me what it was you were asked to do?</p> <p>20 A. I can. I mean --</p> <p>21 Q. Then tell me without looking at the report.</p> <p>22 A. I would qualify that this is just from</p>
<p style="text-align: right;">Page 456</p> <p>1 Roxane engagement?</p> <p>2 A. I believe I did and we returned that to the</p> <p>3 government. And I believe it was disclosed to you.</p> <p>4 Q. Does that form describe exactly what it is</p> <p>5 you're going to do in this case?</p> <p>6 A. I think it just gave a general description</p> <p>7 of the task. I don't think it --</p> <p>8 Q. And what was the general description of the</p> <p>9 task you performed here?</p> <p>10 A. I don't remember. We'd have to look at the</p> <p>11 form that I believe you have and I'd be glad to review</p> <p>12 it and see what it says.</p> <p>13 Q. Okay. Tell me what exactly you were asked</p> <p>14 to do as an expert in this case.</p> <p>15 A. That's stated in my report, again.</p> <p>16 Q. I'd like you to tell me from your own</p> <p>17 memory as best you can recall without looking at your</p> <p>18 report.</p> <p>19 A. I'd prefer to use my report to be accurate.</p> <p>20 Q. I'm sorry. You have to answer the</p> <p>21 questions as they're posed. Please tell me as best</p> <p>22 you can recall during the discussions with Mr. Breen</p>	<p style="text-align: right;">Page 458</p> <p>1 recollection.</p> <p>2 MR. BREEN: Excuse me. Objection, form.</p> <p>3 A. I would qualify that I'm giving an answer</p> <p>4 from recollection at your request. But my report does</p> <p>5 represent what I was asked to do. As best I recall it</p> <p>6 includes the same general types of things I was asked</p> <p>7 to do in the Abbott case, provide an overview of the</p> <p>8 pharmaceutical market, an overview of the Medicare and</p> <p>9 Medicaid programs, an overview of their reimbursement</p> <p>10 and payment processes, a description and overview of</p> <p>11 the role that commercial drug price databases play in</p> <p>12 that marketplace, a description of how the price</p> <p>13 information gets into those drug price databases, a</p> <p>14 review of the documents within each of the respective</p> <p>15 companies, Dey and Roxane, with respect to their role</p> <p>16 and reporting prices and their understanding of those</p> <p>17 broader market conditions that I've described, and how</p> <p>18 they -- what they understood about that market and how</p> <p>19 those prices and list prices affected the payment</p> <p>20 system in third parties in general and in Medicare and</p> <p>21 Medicaid in particular and then an opinion about the</p> <p>22 impact that that would have on the Medicare and</p>

22 (Pages 455 to 458)

Schondelmeyer, Pharm.D., Ph.D., Stephen W. - Vol. II

Washington, DC

February 26, 2009

<p style="text-align: right;">Page 459</p> <p>1 Medicaid programs.</p> <p>2 And there may be other things that are</p> <p>3 specified in my report that I don't recall right now.</p> <p>4 Q. So you were asked to opine on what Dey and</p> <p>5 Roxane understood?</p> <p>6 MS. BROOKER: Objection, form.</p> <p>7 A. Again, I'm doing this from memory. That</p> <p>8 probably isn't the way it's phrased.</p> <p>9 Q. Well, tell me how it's phrased.</p> <p>10 A. Well, I would be glad to if you let me look</p> <p>11 in my report. I don't recall. That's just a general</p> <p>12 description you asked me to give from recollection</p> <p>13 which I qualified as probably not completely accurate</p> <p>14 because my report states what I was asked to do.</p> <p>15 Would you like me to look at that and clarify that?</p> <p>16 Q. Do you consider yourself to be a scholar?</p> <p>17 A. Yes, I do.</p> <p>18 Q. What aspect of your scholarly discipline</p> <p>19 would enable you to opine on what a company understood</p> <p>20 about something?</p> <p>21 MS. BROOKER: Objection, form.</p> <p>22 A. I told you I probably wouldn't have used</p>	<p style="text-align: right;">Page 461</p> <p>1 know what a defendant knew?</p> <p>2 MS. BROOKER: Objection, form.</p> <p>3 MR. BREEN: Objection, form.</p> <p>4 A. I looked at documents that the company</p> <p>5 produced and reviewed them for their face value.</p> <p>6 Q. All right. Let me try the question a</p> <p>7 little different. I think I understand your answer.</p> <p>8 I'm not trying to argue with you. What is it you</p> <p>9 bring to bear reviewing these documents that a</p> <p>10 layperson wouldn't be able to bring to bear in terms</p> <p>11 of reviewing these documents and determining what it</p> <p>12 was a company knew?</p> <p>13 MS. BROOKER: Objection.</p> <p>14 A. I bring to bear 30 years of experience in</p> <p>15 the pharmaceutical marketplace observing and studying</p> <p>16 that marketplace, knowing the very complex terminology</p> <p>17 and complex and detailed way in which this marketplace</p> <p>18 works, the unique terminology and language that's used</p> <p>19 that most people might not understand or understand in</p> <p>20 the way that it would be used within the marketplace,</p> <p>21 the types of terminologies, behaviors, processes,</p> <p>22 descriptions that would be present in documents.</p>
<p style="text-align: right;">Page 460</p> <p>1 the word "understood" about that. I was asked to look</p> <p>2 at documents from the company and identify to what</p> <p>3 degree that company's communications showed evidence</p> <p>4 that they were aware of the processes and the role of</p> <p>5 the list price information.</p> <p>6 Q. So you were asked to evaluate evidence of</p> <p>7 the company?</p> <p>8 A. Yes, I was asked to evaluate evidence of</p> <p>9 the company.</p> <p>10 Q. And you were asked to draw conclusions</p> <p>11 about what the company knew based on that evidence?</p> <p>12 MS. BROOKER: Objection, form.</p> <p>13 A. I identified things that the company knew</p> <p>14 and behaviors that they took and was asked to describe</p> <p>15 those behaviors and their consequences.</p> <p>16 Q. And that was based on the documents from</p> <p>17 the company that you looked at?</p> <p>18 A. I have described in my report what that's</p> <p>19 based on, yes.</p> <p>20 Q. Okay. Well, again, what scholarly</p> <p>21 discipline or knowledge did you bring to bear in terms</p> <p>22 of reviewing the documents in terms of enabling you to</p>	<p style="text-align: right;">Page 462</p> <p>1 So I bring together an expertise and an</p> <p>2 understanding about this marketplace and how it works</p> <p>3 and the behavior of companies in terms of their</p> <p>4 marketing, pricing behaviors in the pharmaceutical</p> <p>5 environment that a normal layperson wouldn't have.</p> <p>6 Q. Can you give me an example of in Dey's case</p> <p>7 a document that Dey had that you looked at that the</p> <p>8 average layperson wouldn't have been able to</p> <p>9 understand but that you were able to understand by</p> <p>10 virtue of your expertise?</p> <p>11 MR. BREEN: Objection, form.</p> <p>12 A. I'd have to look back at the ones I</p> <p>13 reviewed and examine that. I think there are</p> <p>14 different levels at which laypeople can understand</p> <p>15 things and levels at which they cannot. The</p> <p>16 terminology in pharmaceuticals alone is very complex.</p> <p>17 Q. So some of the documents referenced in your</p> <p>18 report a layperson could understand like a jury?</p> <p>19 MS. BROOKER: Objection, form.</p> <p>20 A. I believe with contextual description of</p> <p>21 the marketplace jurors certainly could understand</p> <p>22 everything that's here. But I think --</p>

23 (Pages 459 to 462)

<p style="text-align: right;">Page 463</p> <p>1 Q. So you could tell them how the marketplace 2 works -- 3 A. May I finish my answer? 4 But I think the jurors need a broader 5 context to place those documents in to understand how 6 the broader system works above and beyond Dey and 7 above and beyond Roxane to put in context what's 8 discussed in those documents. 9 Q. So while you can maybe provide a context 10 you really can't offer the jury any assistance in what 11 any defendant knew in this case? 12 MS. BROOKER: Objection, form. 13 A. I believe by the level and degree to which 14 information is presented, used, if I see information 15 that Dey or Roxane engaged in training programs for 16 their employees about reimbursement systems I think I 17 can represent that Dey knew and understood the role of 18 reimbursement systems in the marketplace and the role 19 that various prices played in that reimbursements and 20 the consequences that would result from setting a 21 price one way versus another. 22 I can bring that to the table, yes. I can</p>	<p style="text-align: right;">Page 465</p> <p>1 A. That was Upjohn in Kalamazoo, Michigan. 2 Q. And what kind of drugs does Upjohn sell in 3 the program that you were involved in? 4 A. I'm sorry. What was? 5 Q. Were they a generic manufacturer? Were 6 they a brand manufacturer? 7 A. Upjohn had brand and generics. 8 Q. And can you explain to me what your 9 experience selling generic drugs is, if any? 10 A. I've provided consulting and worked with a 11 number of generic companies. 12 Q. Which ones? 13 A. Over time, many. Ethex, KV 14 Pharmaceuticals, Teva, Apotex, who is the other one in 15 Canada. Novopharm. It was in the U.S. market as 16 well. Upsher-Smith, Paddock Labs and probably a 17 number of others. Those are the ones I recall. 18 Q. What have you done to assist them in 19 connection with sales? 20 A. I've provided presentations to their sales 21 and marketing and executive staffs on the 22 pharmaceutical market, on pricing issues, on the role</p>
<p style="text-align: right;">Page 464</p> <p>1 describe that. 2 Q. But can you tell me, though, which of the 3 documents you feel that's in your report that the jury 4 would require your assistance to interpret? 5 MS. BROOKER: Objection, form. 6 A. I think all the documents listed in my 7 report the jury could read and probably would come to 8 the same conclusions I have about them. 9 Q. Okay. Now, have you had any training in 10 marketing? 11 A. Yes, I have. 12 Q. What training have you had in marketing? 13 A. I've had courses in marketing in my Ph.D. 14 program, marketing -- a general marketing course, a 15 healthcare marketing course, a pharmaceutical 16 marketing course. 17 Q. Do you have any sales training? 18 A. I have sales training. I went through part 19 of the sales training of a pharmaceutical company when 20 I was -- did a faculty exchange program with a 21 pharmaceutical company one summer. 22 Q. Which company was that?</p>	<p style="text-align: right;">Page 466</p> <p>1 of pricing and marketing. 2 Q. And what kind of advice do you give in that 3 connection? 4 A. I describe the market and how things work. 5 I don't -- you know, I usually give generally talks 6 and then we have a question and answer period and they 7 ask things that are of interest to them. 8 Q. Do you have sales materials you use for 9 those programs? Do you have presentations that you 10 have that are written down? 11 A. I probably have a series of Power Point 12 slides. I don't use sales material per se. 13 Q. When last did you do one of these 14 presentations for a manufacturer? 15 A. Probably a year ago. 16 Q. Did you discuss things in your 17 presentations like marketing the spread and so forth? 18 MS. BROOKER: Objection, form. 19 A. It depends on the presentation and what 20 I've been asked to do. Sometimes they ask me to come 21 and give a presentation on what's happening, the 22 dynamic flux in the marketplace, what kind of things</p>

24 (Pages 463 to 466)

Schondelmeyer, Pharm.D., Ph.D., Stephen W. - Vol. II

February 26, 2009

Washington, DC

<p style="text-align: right;">Page 487</p> <p>1 THE WITNESS: Can you read that back? He</p> <p>2 had several clauses there. I'm not sure I understood.</p> <p>3 MR. MERKL: All right. Let me try to make</p> <p>4 it simpler then.</p> <p>5 THE WITNESS: Okay.</p> <p>6 MR. MERKL: I'll withdraw that.</p> <p>7 BY MR. MERKL:</p> <p>8 Q. The phrase "reasonable dispensing fee" that</p> <p>9 you're using there in the sentence -- okay? Do you</p> <p>10 see that phrase there? All right. The dispensing fee</p> <p>11 you're talking about there is the dispensing fee</p> <p>12 that's used in the reimbursement formula --</p> <p>13 MS. BROOKER: Objection, form.</p> <p>14 Q. -- the concept?</p> <p>15 A. Yes.</p> <p>16 Q. Okay. Now, you say "Medicaid program</p> <p>17 materials describe a 'reasonable dispensing fee,'"</p> <p>18 correct?</p> <p>19 A. If does say that, yeah.</p> <p>20 Q. So there are Medicaid program materials</p> <p>21 that tell us how a dispensing fee has to be put</p> <p>22 together?</p>	<p style="text-align: right;">Page 489</p> <p>1 figure out what a reasonable dispensing fee should be</p> <p>2 that components of that have to include the pharmacy's</p> <p>3 overhead and profit; is that correct?</p> <p>4 A. It tells us that a dispensing fee is an</p> <p>5 established fee to cover a pharmacy's overhead and</p> <p>6 profit.</p> <p>7 Q. Now, when they decided what was in the</p> <p>8 dispensing fee -- I'm asking you I guess to put on</p> <p>9 your kind of expert hat here now -- can you tell me</p> <p>10 why they decided they wanted to put profit in as an</p> <p>11 element of the dispensing fee? I mean, I'm sure --</p> <p>12 was it just pharmacists lobbying for this or was there</p> <p>13 a valid policy reason why you would want to have</p> <p>14 profit to be part of the dispensing fee?</p> <p>15 MS. BROOKER: Objection, form.</p> <p>16 A. I think a statement like this that profit</p> <p>17 is a consideration. It doesn't say they're required</p> <p>18 to. But it does say it's part of an established -- it</p> <p>19 doesn't say how much or how they determine that.</p> <p>20 Q. Agreed.</p> <p>21 A. But it's listed there. I think it's a</p> <p>22 recognition that part of the U.S. healthcare delivery</p>
<p style="text-align: right;">Page 488</p> <p>1 MS. BROOKER: Objection, form.</p> <p>2 A. There are descriptive materials about what</p> <p>3 a dispensing fee is and what it includes and that's</p> <p>4 what I've quoted here.</p> <p>5 Q. Can you tell me what those materials you're</p> <p>6 referring to here are?</p> <p>7 A. What those materials are?</p> <p>8 Q. Yeah.</p> <p>9 A. Well, I've quoted where that comes from.</p> <p>10 And it comes from this source, the National</p> <p>11 Pharmaceutical Council. And within that document we'd</p> <p>12 have to look and see. That document often -- a number</p> <p>13 of pages in the National Pharmaceutical Council book</p> <p>14 each year are either Federal Register notices from the</p> <p>15 government or other Medicaid program materials and</p> <p>16 other materials.</p> <p>17 Q. So your citation there represents this</p> <p>18 document which is a compilation of different federal</p> <p>19 Medicaid materials?</p> <p>20 A. And other things.</p> <p>21 Q. And what this then tells us is when you're</p> <p>22 trying to figure out or when the state is trying to</p>	<p style="text-align: right;">Page 490</p> <p>1 system that provides outpatient prescriptions to the</p> <p>2 public and in this case to Medicaid recipients are</p> <p>3 typically community pharmacies, independents, chains,</p> <p>4 grocery stores, you know, mass merchandisers. But all</p> <p>5 of those are private business entities that are in the</p> <p>6 marketplace for profits, you know, small businesses,</p> <p>7 large businesses.</p> <p>8 And I think it's just a recognition that if</p> <p>9 one said Medicaid's policy was to never pay a cent of</p> <p>10 profit then they probably wouldn't have providers in</p> <p>11 that marketplace.</p> <p>12 Q. Okay. Thank you. I'd like to take a look</p> <p>13 at page 4 now. At the bottom of page 4 it has sources</p> <p>14 of growth in Medicaid drug expenditures. And I gather</p> <p>15 from '92 to 2002 the Medicaid drug benefit cost was</p> <p>16 expanding. Is that correct?</p> <p>17 A. That would be fair to say, yes.</p> <p>18 Q. And the cost of drugs was expanding?</p> <p>19 A. Well, the expenditures for drugs is what</p> <p>20 this addresses, primarily. It doesn't talk about --</p> <p>21 Q. My mistake. Expenditures is a better word.</p> <p>22 So the expenditures for drugs were expanding and</p>

30 (Pages 487 to 490)

Schondelmeyer, Pharm.D., Ph.D., Stephen W. - Vol. II

February 26, 2009

Washington, DC

<p style="text-align: right;">Page 491</p> <p>1 there's a number of factors that go into that, right?</p> <p>2 A. Yes.</p> <p>3 Q. Can you tell me the factors that went into</p> <p>4 that, why these drugs expenditures were expanding from</p> <p>5 '92 to 2002, in your own words?</p> <p>6 MS. BROOKER: Objection, form.</p> <p>7 A. I can in my own words or we could look at</p> <p>8 the chart on the next page. It demonstrates it very</p> <p>9 well.</p> <p>10 Q. We'll go to the chart on the next page in</p> <p>11 just a second.</p> <p>12 A. Yeah.</p> <p>13 Q. Okay. If you want to look at it, fine.</p> <p>14 But just give me an idea --</p> <p>15 A. I know that pretty well.</p> <p>16 MS. BROOKER: You're talking over each</p> <p>17 other. Both. Really, you have to wait for a</p> <p>18 question. Please wait for his answer.</p> <p>19 BY MR. MERKL:</p> <p>20 Q. Just in general terms why was drug</p> <p>21 expenditures going up from '92 to '02? If you'd like</p> <p>22 to look at the chart that's fine.</p>	<p style="text-align: right;">Page 493</p> <p>1 And the cost per prescription could be looked at in</p> <p>2 its aggregate or it could be looked at in the two</p> <p>3 components that make it up. That is, the ingredient</p> <p>4 cost of the drug product plus the dispensing fee</p> <p>5 and/or compensation to the pharmacist.</p> <p>6 Q. Did you look at that here?</p> <p>7 A. Yes, I did.</p> <p>8 Q. And what did you find?</p> <p>9 A. That the manufacturer drug product cost as</p> <p>10 paid by Medicaid was going up substantially. I don't</p> <p>11 remember what it was. About 140 percent, 137 percent.</p> <p>12 And that the dispensing fees to pharmacists -- all of</p> <p>13 these were adjusted for constant dollars over time.</p> <p>14 The dispensing fees to pharmacists were down 20</p> <p>15 percent over the decade 1992 to 2002.</p> <p>16 Q. Now, you say you adjusted it for constant</p> <p>17 dollars. Can you explain to the jury what that means</p> <p>18 and why it's an advantage to do it that way?</p> <p>19 A. Well, it's not that either is right or</p> <p>20 wrong. It just gives a different perspective and</p> <p>21 information on the value of things. Constant dollars</p> <p>22 are -- first of all, if I said I'll give you a</p>
<p style="text-align: right;">Page 492</p> <p>1 A. There are a variety of functions that drive</p> <p>2 the equation of total drug expenditures in the</p> <p>3 population and in Medicaid in particular. First is</p> <p>4 the number of persons covered. With respect to</p> <p>5 Medicaid between 1992 and 2002 there was an expansion</p> <p>6 of the number of people covered by Medicaid programs</p> <p>7 in the U.S. That expansion was about 60 percent --</p> <p>8 59, 60 percent.</p> <p>9 So one factor was -- no. Actually it</p> <p>10 wasn't that much. The utilization was 60 percent.</p> <p>11 About 5.6 percent increase in the number of recipients</p> <p>12 in that ten year time period.</p> <p>13 The second factor that affects the drug</p> <p>14 expenditure equation is what we call utilization. A</p> <p>15 simplistic way to describe utilization is the number</p> <p>16 of prescriptions per person per year. And that</p> <p>17 number, the utilization, prescriptions per person per</p> <p>18 year, did increase by about 59 or 60 percent.</p> <p>19 So we had a slight increase in the number</p> <p>20 of people covered, a 60 percent increase in the</p> <p>21 prescriptions for person per year. The next component</p> <p>22 is -- we can look at as the cost per prescription.</p>	<p style="text-align: right;">Page 494</p> <p>1 thousand dollars today or a thousand dollars in five</p> <p>2 years and asked people which they want most people</p> <p>3 would say well, give me the thousand dollars today</p> <p>4 because it's going to be worth more than a thousand</p> <p>5 dollars in five years because in general in society --</p> <p>6 although, again, I would caution that in today's</p> <p>7 environment I don't know what would happen.</p> <p>8 But in general society over time things</p> <p>9 tend to cost us more. And so adjusting for constant</p> <p>10 dollars is a way of looking at the amount paid for</p> <p>11 something over time and trying to put it in equivalent</p> <p>12 dollars for any point in time. So in this case we</p> <p>13 adjusted for constant dollars. So it takes out -- and</p> <p>14 I used the generate of inflation using the consumer</p> <p>15 price index inflator to do that.</p> <p>16 Q. Well, let's turn to your chart. You can</p> <p>17 assume I guess in terms of answering these question</p> <p>18 that the chart will be on a screen and the courtroom</p> <p>19 can see it. Okay?</p> <p>20 A. Mm-hmm.</p> <p>21 Q. Now, in that first column there about the</p> <p>22 drug expense, that's kind of the raw cost of all the</p>

31 (Pages 491 to 494)

<p style="text-align: right;">Page 499</p> <p>1 percent, would not be as high, and the rate of 2 increase in the average payment per Rx would not be as 3 high and the rate of increase in the drug product 4 payment per Rx would not be as high. 5 Q. Now, what if Dey in fact lowered its prices 6 over time, its WAC, for instance, over time, 7 regularly, steadily, to follow its sales down? Then 8 what would happen? 9 MS. BROOKER: Objection, form. 10 A. If Dey lowered their WAC that was reported, 11 if it was reported -- 12 Q. Reported, yeah. 13 A. -- and was lowered, it would have brought 14 this average down some. But if it wasn't lowered as 15 much as their actual selling prices went down then the 16 full effect of that would not have been realized. 17 Q. But Dey lowering its WAC would help reduce 18 costs overall then, not just for Dey? 19 MS. BROOKER: Objection, form. 20 A. Well, it would have only affected Dey's 21 particular products in most cases. 22 Q. Well, I understand. You were telling me</p>	<p style="text-align: right;">Page 501</p> <p>1 things off so we don't have to talk about them. So am 2 I correct that you have not done an analysis for 3 either Dey or Roxane showing the impact of their 4 pricing on overall market expenditures? 5 MS. BROOKER: Objection, form. 6 Q. It's not an analysis you've done for this 7 report? 8 A. I've done a qualitative assessment of their 9 behaviors and the impacts on the market. I've not 10 done a quantitative assessment as Professor Duggan 11 has. 12 Q. So you can't really comment on whether 13 anything Dey did caused overall expenditures to go up 14 or down? 15 A. In a qualitative sense I can, yes. In a 16 quantitative -- I didn't attempt to quantify it. 17 Q. Right. You couldn't tell me whether it's 18 \$1 or \$10 million? 19 MS. BROOKER: Objection, form. 20 A. Well, I didn't address that in my report. 21 I could probably give you an order of magnitude and 22 address that based on the broad behaviors. But I</p>
<p style="text-align: right;">Page 500</p> <p>1 earlier that if you reported a list price that wasn't 2 correct it could be ramifications and cause other 3 problems in the program. Now, I guess what I'm asking 4 you is if in fact Dey reported a declining WAC for its 5 drugs, not only would that help reduce the cost of 6 Dey's drugs actually, but it would also have a 7 positive effect in reducing the costs on other drugs 8 as long as we're talking about the same drugs, 9 albuterol, cromolyn and ipratropium, right? 10 A. It may or may not have had an effect on 11 other drugs. It depends on how many products were in 12 a given category and whether it affected the kind of 13 median AWP's or other things, if these were reimbursed 14 under J-code type payments or if these were reimbursed 15 under Medicaid type payments. So it depends. You 16 have to qualify that. 17 Q. All right. Well, did you do that analysis? 18 MS. BROOKER: Objection, form. 19 A. I did not do any quantitative analysis in 20 this report. I did a qualitative assessment of the 21 impact. 22 Q. Yeah. I'm just trying to kind of wall</p>	<p style="text-align: right;">Page 502</p> <p>1 didn't attempt to specifically come up with an amount 2 or a change. Again, that was -- 3 Q. Outside the scope of your -- 4 A. -- not a task I was asked to do. 5 Q. Now, taking a look at your report for this 6 time period, from '92 to 2002 there was inflation 7 going on, right? 8 A. There was inflation, yes, in the general 9 economy. 10 Q. And I guess I'm looking now about the 11 dispensing fee payment description? 12 A. Yes. 13 Q. In terms of what you're representing here 14 what items conceptually go in or should be considered 15 in setting the dispensing fee payment description that 16 you're discussing here conceptually? 17 A. In who setting it? The pharmacy or 18 Medicaid program? Those are different. 19 Q. Well, let me ask you. The chart here shows 20 dispensing fees minus 20.2 percent, right? So it 21 says. 22 A. Dispensing fee payment per Rx.</p>

Schondelmeyer, Pharm.D., Ph.D., Stephen W. - Vol. II

February 26, 2009

Washington, DC

<p style="text-align: right;">Page 519</p> <p>1 and Roxane drugs if you're getting it from other 2 sources? 3 A. That as good question. Because the 4 manufacturer -- pharmacists are unique from most of 5 the products in the market. Because these are, quote, 6 dangerous substances and by law we require tracking of 7 the sales of all pharmaceuticals at all levels, 8 prescription pharmaceuticals in particular, a 9 manufacturer has to keep a record of each sale. 10 And I'm familiar with being involved in 11 that as an expert and in many cases over time familiar 12 with the types of pricing and sales databases that 13 drug companies keep. And they keep very detailed 14 records of each customer they sold and how much and at 15 what price and what the AWP and WAC and actual price 16 and discounts and rebates -- and all that detail is 17 there. This is electronic. It is available. 18 And whether the manufacturer sells to a 19 wholesaler or sells to the pharmacy direct or to a 20 group purchasing organization that on paper gets the 21 product but has a wholesaler process anyway, those all 22 involve contracts and the manufacturer has the data to</p>	<p style="text-align: right;">Page 521</p> <p>1 A. Well, you can, because manufacturers when 2 they sell to wholesaler have a contract with the 3 wholesaler. They know the wholesaler's prices going 4 through. If they sell to a group purchasing 5 organization they have a contract with the group 6 purchasing organization that specifies what the sales 7 price is. A manufacturer does have the sales price. 8 Q. But again, both the GPOs and the 9 wholesalers mark up their prices when they sell to the 10 retailers, don't they? 11 A. But that's known -- the manufacturer knows 12 that information. That's not hidden from them. 13 Q. You think the manufacturer knows what the 14 wholesalers sell? 15 A. Yes. 16 Q. And what do you base that on? 17 A. Wholesalers and manufacturers and databases 18 that capture that information. 19 Q. Let me then come back to our case, Dey and 20 Roxane. What evidence did you see that told you that 21 Dey and Roxane knew how much their wholesalers were 22 charging the providers for their drugs?</p>
<p style="text-align: right;">Page 520</p> <p>1 know how that product flows through the system. So 2 there are fewer manufacturers. There may be 8 to a 3 hundred to a thousand pharmaceutical manufacturers. 4 I think if we looked at the participants in 5 the Medicaid drug rebate program, it's probably 600 or 6 thereabouts manufacturers. So there are only like 600 7 manufacturers that would capture all transactions from 8 that source, versus going to 60,000 pharmacies to try 9 to get the same information. And they may have 10 different ways of accounting for and tracking things 11 and they may have difficult identifying how much 12 rebate is coming in at what point in time. 13 It's much easier to track. There are fewer 14 transaction points and variables and differences at 15 the manufacturer level than there are as you go 16 further down the line. Yet you can get all the detail 17 to describe everything that happened after it left the 18 manufacturer in most cases. 19 Q. But unless the manufacturer actually sells 20 direct to the pharmacy you don't know what the 21 pharmacy paid? You can't get that information from 22 the manufacturer, can you?</p>	<p style="text-align: right;">Page 522</p> <p>1 A. I didn't address that issue. I wasn't 2 asked to. It wasn't relevant in preparing my report. 3 Q. So you don't know? 4 MS. BROOKER: Objection, form. 5 A. So I didn't address that in this particular 6 case. 7 Q. So you don't really know if that happened 8 for Dey and Roxane? 9 A. I don't know for certain. But I believe 10 that to be true. 11 Q. And you can't point me to any evidence that 12 your belief is based on in the hands of Dey and 13 Roxane? 14 MS. BROOKER: Objection, form. 15 A. I did not specifically evaluate that 16 because it wasn't underpinning any of my opinions in 17 the case. But I would be extremely surprised if it 18 wasn't true. 19 Q. Now, let's take a look at your next chart. 20 Can you tell me when your next chart is? That's the 21 chart on page 6. 22 A. Just describe it? What's the question?</p>

38 (Pages 519 to 522)

<p style="text-align: right;">Page 523</p> <p>1 Q. First, did you prepare this chart?</p> <p>2 A. Yes, I did.</p> <p>3 Q. And what does this chart tell us?</p> <p>4 A. Well, as the title describes, it's the U.S.</p> <p>5 Medicaid average prescription payment, so the average</p> <p>6 total prescription price under U.S. Medicaid, and each</p> <p>7 column in this chart for a given year has three</p> <p>8 components to it. One is the dispensing fee payment</p> <p>9 component. One is the drug product or ingredient cost</p> <p>10 payment component. And the third part is the rebate</p> <p>11 amount.</p> <p>12 Q. And you prepared this based on data that</p> <p>13 you reviewed?</p> <p>14 A. Based on data from government sources and I</p> <p>15 prepared, yes.</p> <p>16 Q. And again -- I'm sorry if I already asked</p> <p>17 you this -- but to the best of your knowledge this</p> <p>18 chart and the prior chart we just looked at are true</p> <p>19 and accurate descriptions of the data as you saw it at</p> <p>20 the time?</p> <p>21 A. Yes.</p> <p>22 Q. Now, below the chart -- and again, this</p>	<p style="text-align: right;">Page 525</p> <p>1 A. She has a significant role in Medicaid</p> <p>2 policy at CMS.</p> <p>3 Q. And her duties include Medicaid</p> <p>4 reimbursement for drugs, right?</p> <p>5 A. In some sense, yes.</p> <p>6 Q. Now, here you say "The payment amount for</p> <p>7 drug products to pharmacies and other providers under</p> <p>8 Medicaid and Medicare cannot be viewed in isolation</p> <p>9 from the other payments to such providers for storage,</p> <p>10 handling, counseling, dispensing, billing, record</p> <p>11 keeping and administration." That's true, right?</p> <p>12 A. That's what this says, yes.</p> <p>13 Q. Well, and you agree that's still a true</p> <p>14 fact, right?</p> <p>15 A. I do, based on the definitions that are</p> <p>16 described here, yes.</p> <p>17 Q. Okay. It says "In both the Medicaid and</p> <p>18 the Medicare program drug payment policy incorporates</p> <p>19 two components: a component directly representing the</p> <p>20 cost of professional services and a component</p> <p>21 representing drug costs." Again, correct? We've just</p> <p>22 been through that, right?</p>
<p style="text-align: right;">Page 524</p> <p>1 chart and this report is being presented to I guess</p> <p>2 CMS. Am I correct?</p> <p>3 A. They were the contractor that requested the</p> <p>4 report, yes.</p> <p>5 Q. And in particular the woman's name is</p> <p>6 Deirdra Duzor?</p> <p>7 A. Duzor, yes.</p> <p>8 Q. And can you tell the jury who Deirdra Duzor</p> <p>9 is?</p> <p>10 A. I don't remember her exact title. Her role</p> <p>11 is over Medicaid policy with respect to</p> <p>12 pharmaceuticals. She is one of -- not the only</p> <p>13 person. Larry Reed is another person this works with</p> <p>14 her.</p> <p>15 Q. Mr. Reed works for Mr. Duzor, right?</p> <p>16 A. I don't recall who role they're in</p> <p>17 necessarily. And they both report to the head of CMS.</p> <p>18 Q. And who's that?</p> <p>19 A. I don't recall at this point in time.</p> <p>20 Q. But Ms. Duzor was someone with principal</p> <p>21 oversight responsibility for the Medicaid program at</p> <p>22 the time you prepared this report?</p>	<p style="text-align: right;">Page 526</p> <p>1 A. It does. And I qualify the cost of</p> <p>2 professional services here is limited to the cost of</p> <p>3 professional services involved with the broader aspect</p> <p>4 of a dispensing a prescription, which includes the</p> <p>5 required counseling under OBRA '90. It doesn't</p> <p>6 necessarily include all professional services that</p> <p>7 might be delivered. Those would be yet a third</p> <p>8 component rather than the two as described here.</p> <p>9 If a pharmacist or a provider provides</p> <p>10 additional professional services beyond those required</p> <p>11 with typical dispensing, as I've described here, then</p> <p>12 there would be a third component or a cost of services</p> <p>13 that would need to be accounted for.</p> <p>14 Q. Yeah. I missed that before. Before when</p> <p>15 you explained to me the costs that went into the</p> <p>16 dispensing fee was this cost of this services</p> <p>17 counseling concept that you've just explained to me,</p> <p>18 was that included in that or was that a third one we</p> <p>19 didn't consider?</p> <p>20 A. Well, wait. You're muddling even now what</p> <p>21 I said.</p> <p>22 Q. Okay.</p>

<p style="text-align: right;">Page 527</p> <p>1 A. The counseling listed here does go into the</p> <p>2 cost of dispensing.</p> <p>3 Q. Okay.</p> <p>4 A. To the degree that that counseling is the</p> <p>5 counseling that's required under OBRA '90 that says</p> <p>6 you must counsel a patient on -- there's in OBRA '90 a</p> <p>7 specific definition of counseling. It's not all</p> <p>8 counseling or all patient education or all care</p> <p>9 management. That's a separate issue that -- under</p> <p>10 Medicare now for example we call it medication therapy</p> <p>11 management. And I've conducted of number of studies</p> <p>12 identifying the cost of providing medication therapy</p> <p>13 management or other professional services and</p> <p>14 identifying the outcome and the impact that they have</p> <p>15 on patient care and other things.</p> <p>16 But that's a separate cost that's not</p> <p>17 incorporated in this particular statement.</p> <p>18 Q. Okay. But it is a cost that the pharmacist</p> <p>19 has in connection with dispensing Medicaid drugs?</p> <p>20 A. It's a cost the pharmacist has that's in</p> <p>21 addition to dispensing. And again, it may or may not</p> <p>22 be required or covered by a given third party program,</p>	<p style="text-align: right;">Page 529</p> <p>1 MS. BROOKER: Objection, form.</p> <p>2 A. I think it's good pharmacy practice to</p> <p>3 provide it. But you have to assure that there's</p> <p>4 coverage and appropriate compensation. Just providing</p> <p>5 it without having it paid for means that the pharmacy</p> <p>6 also might be going out of business because they're</p> <p>7 incurring expenses. But that doesn't obligate a third</p> <p>8 party to pay you.</p> <p>9 Q. Okay. Now, the next sentence "Note that</p> <p>10 deliberately or not the drug cost component of the</p> <p>11 payment has typically offered a margin relative to</p> <p>12 acquisition cost."</p> <p>13 A. I'm sorry. Where are you? I don't --</p> <p>14 Q. I'm reading the next sentence.</p> <p>15 A. Oh. "Note that." You left off the --</p> <p>16 Q. I'm sorry. Well, let me start again. The</p> <p>17 next sentence says "Note that deliberately or not the</p> <p>18 drug cost component of the payment has typically</p> <p>19 offered a margin relative to acquisition cost." And</p> <p>20 again, that's true, correct?</p> <p>21 A. That is true.</p> <p>22 Q. And I'm not trying to suggest it's by</p>
<p style="text-align: right;">Page 528</p> <p>1 whether it be a private insurer or Medicare or</p> <p>2 Medicaid. Some require it. Some cover it. Some say</p> <p>3 it's fine did you if you do it, but it's not a covered</p> <p>4 service.</p> <p>5 Q. Is that service typically factored in when</p> <p>6 the states set dispensing fees under Medicaid?</p> <p>7 A. No.</p> <p>8 MS. BROOKER: Objection, form.</p> <p>9 Q. But it still is a service they have to</p> <p>10 provide?</p> <p>11 A. No. They have to provide the OBRA '90</p> <p>12 counseling that's in the dispensing fee.</p> <p>13 Q. Right.</p> <p>14 A. The other Medicaid therapy management is</p> <p>15 not a service that pharmacies have to provide. It's</p> <p>16 not a normal -- it's an additional service that could</p> <p>17 be provided. But it's not always covered or paid for</p> <p>18 by a third party program, including Medicaid or</p> <p>19 Medicare in all cases.</p> <p>20 Q. Even though it's not always covered or paid</p> <p>21 for, in your view is it a good pharmacy practice for</p> <p>22 the pharmacist to provide that service?</p>	<p style="text-align: right;">Page 530</p> <p>1 design. But it was the state of affairs that that is</p> <p>2 what you discovered had been happening in the market,</p> <p>3 correct?</p> <p>4 MS. BROOKER: Objection, form.</p> <p>5 A. That is at the point in time this study was</p> <p>6 done, 2004, what we discovered. And I would point out</p> <p>7 that in general it's a relatively unknown margin.</p> <p>8 There is a margin, and there is some sense that it's</p> <p>9 there. But the exact quantity of that is not</p> <p>10 typically known to third party or a Medicaid</p> <p>11 officials.</p> <p>12 Q. But the pharmacists know what that margin</p> <p>13 is?</p> <p>14 A. They may know for their individual</p> <p>15 pharmacy. They may know.</p> <p>16 Q. And then you continue. You say "This may</p> <p>17 be appropriate since certain other costs (such as drug</p> <p>18 inventory and storage, accounts receivable,</p> <p>19 uncollectible claims and copays, and the cost of</p> <p>20 capital) vary in proportion to the cost of the drug."</p> <p>21 Was that your view at the time?</p> <p>22 A. It was my view at the time, yes.</p>

40 (Pages 527 to 530)

Schondelmeyer, Pharm.D., Ph.D., Stephen W. - Vol. II

February 26, 2009

Washington, DC

<p style="text-align: right;">Page 535</p> <p>1 Q. Fine. Do they ask for any other data?</p> <p>2 A. Again, that's all that Congress authorized</p> <p>3 them to ask for.</p> <p>4 Q. So all this other information that you say</p> <p>5 that would be helpful to set prices they could have</p> <p>6 asked for in this contract, but they didn't, right?</p> <p>7 MS. BROOKER: Objection, form.</p> <p>8 A. Well, again, the long-standing requests of</p> <p>9 the estimated acquisition cost -- the long-standing</p> <p>10 policy of estimated acquisition costs and the way in</p> <p>11 which it was implemented was still known and didn't</p> <p>12 change over this time period.</p> <p>13 Q. Well, you keep saying the long-standing</p> <p>14 estimated acquisition cost policy.</p> <p>15 A. Yes.</p> <p>16 Q. While it's a policy, it's not a request or</p> <p>17 a directive in any ordinary English speaking sense</p> <p>18 directed to manufacturers to report particular</p> <p>19 information, is it?</p> <p>20 MR. BREEN: Objection, form.</p> <p>21 A. It's the way in which Medicaid -- let's use</p> <p>22 Medicaid as an example. Medicaid pays for</p>	<p style="text-align: right;">Page 537</p> <p>1 point me to that tells them what exactly they must</p> <p>2 report, is there?</p> <p>3 MR. BREEN: Objection, form.</p> <p>4 A. It doesn't give a complete specificity of</p> <p>5 how you would define that. But I believe one could</p> <p>6 give a plain meaning to generally and currently paid</p> <p>7 by the provider. And I don't see that the prices</p> <p>8 reported by manufacturers fall within that meaning.</p> <p>9 Q. Is there a statute anywhere that tells a</p> <p>10 manufacturer that the manufacturer must report what is</p> <p>11 generally and currently paid by the provider?</p> <p>12 MR. BREEN: Objection, form.</p> <p>13 A. I'd have to look back. I don't recall the</p> <p>14 derivation of that.</p> <p>15 Q. So you can't identify such a statute?</p> <p>16 A. I'd have to look back, yeah.</p> <p>17 Q. And you can't identify a regulation either?</p> <p>18 MR. BREEN: Objection, form.</p> <p>19 A. I'd have to look back and see.</p> <p>20 MS. BROOKER: Can we take a break when you</p> <p>21 get a chance?</p> <p>22 THE WITNESS: I have to go to the bathroom</p>
<p style="text-align: right;">Page 536</p> <p>1 prescription drugs, is made very transparent, so that</p> <p>2 parties whose products may be used by that Medicaid</p> <p>3 program know how that payment will be made and they</p> <p>4 know the factors that go into that payment as well as</p> <p>5 the policy objective that Medicaid has in making those</p> <p>6 payments.</p> <p>7 And by various actions they, without the</p> <p>8 government knowing so, can change the amount the</p> <p>9 government pays for a given product in a way that</p> <p>10 causes the government to pay more than they would</p> <p>11 otherwise if the policy was followed.</p> <p>12 Q. Well, again, though -- you keep saying the</p> <p>13 policy. There's no request or statute telling the</p> <p>14 manufacturers precisely what to report anywhere, is</p> <p>15 there --</p> <p>16 MS. BROOKER: Objection, form.</p> <p>17 Q. -- other than the AMP?</p> <p>18 A. I believe that manufacturers could report</p> <p>19 any price that's generally and currently paid by</p> <p>20 providers in the market. That doesn't appear to be</p> <p>21 what's happened here.</p> <p>22 Q. But there's no statute or rule you can</p>	<p style="text-align: right;">Page 538</p> <p>1 again.</p> <p>2 MR. MERKL: Well, do you want to go to</p> <p>3 12:30 and then go to lunch?</p> <p>4 MS. BROOKER: Yeah, I guess.</p> <p>5 MR. BREEN: It's up to the witness. Do you</p> <p>6 need a break?</p> <p>7 THE WITNESS: I need a restroom break at</p> <p>8 some point. I don't know if 12:30 is -- I can make it</p> <p>9 quick.</p> <p>10 MS. BROOKER: Just a quick restroom break.</p> <p>11 MR. MERKL: All right, fine.</p> <p>12 THE VIDEOGRAPHER: Off the record at 12:08.</p> <p>13 (Recess.)</p> <p>14 THE VIDEOGRAPHER: On the record at 12:15.</p> <p>15 BY MR. MERKL:</p> <p>16 Q. Could you take a look at the chart again?</p> <p>17 A. Sure.</p> <p>18 Q. That's the chart on page 6. You have a</p> <p>19 rebate amount there. What does that signify?</p> <p>20 A. This is the rebate amount that the</p> <p>21 pharmaceutical company has agreed to pay back to the</p> <p>22 Medicaid program for their products that are used in</p>

42 (Pages 535 to 538)

Schondelmeyer, Pharm.D., Ph.D., Stephen W. - Vol. II

February 26, 2009

Washington, DC

<p style="text-align: right;">Page 567</p> <p>1 A. Well, the first sentence says "The brand 2 price product usually does not compete." So this is a 3 generalization, but it's not in all cases. 4 Q. Okay. 5 A. So I wouldn't want to misrepresent that. 6 But the brand typically does not compete on price with 7 generics with their branded version of the product. 8 They may enter with a generic version or an authorized 9 generic that they compete in price. 10 Q. Well, let me just back up. My 11 understanding based on testimony you've given in other 12 cases is that you've basically studied pricing 13 patterns for 25 years, you look at AWP's reported, you 14 follow WACs and you look at all the drugs in the 15 market. True? 16 A. Basically, yes. 17 Q. I'm not trying to suggest that's all you 18 do, but in your areas of expertise that's one of the 19 things you do, right? You observe pricing patterns. 20 I guess my question is based on your observations 21 isn't it fair to say that often, notwithstanding 22 that you may have pretty fierce generic competition</p>	<p style="text-align: right;">Page 569</p> <p>1 goes generic in most of the market generics are used. 2 They're safe. The FDA reviews them and says they're 3 therapeutically equivalent to the brand referenced 4 product. They meet the same standards, the same 5 quality as the brand. 6 So generics are very safe. But in some 7 cases doctors either of their own volition or due to 8 urging and marketing activities of drug companies will 9 specify brand medically necessary. And so there may 10 be cases where the drug company knows I can keep a 11 small sector of the market who continues to use my 12 branded version of this product even though generics 13 are available. And if I say brand medically necessary 14 the consumer doesn't have a choice regardless of what 15 the price difference is. 16 Q. Well, did you observe whether or not that 17 happened with any of the drugs in this case, 18 albuterol, cromolyn, ipratropium? 19 A. Whether or not what happened? We talked 20 about a number of things that were happening there. 21 Q. Well, I assume you observed that the 22 transaction prices went down over time, right, for the</p>
<p style="text-align: right;">Page 568</p> <p>1 for a drug like albuterol or cromolyn that the brand 2 price might very well go up while the generic price 3 goes down; is that true? 4 A. Well, again, my general statement here is 5 that even though the generics compete in price the 6 brand does not. So the brand may stay the same. In 7 some cases it may go up. 8 Q. Why would that happen? Why would the brand 9 be able to go up? 10 A. Well, again, the brand may have -- the 11 pharmaceutical market is different than any other 12 market, consumer market, in that -- for a whole lot of 13 reasons, one of which is that the patient must have a 14 permission slip from a doctor to get it. You can't 15 simply walk in a pharmacy and say I'll have 50 Prozac 16 or I'll have 50 Lipitor. You have to have a 17 prescription. 18 The doctor in writing that prescription by 19 law can specify a specific brand that is brand 20 medically necessary. If the doctor doesn't specify 21 the law allows the pharmacists to substitute a 22 generically equivalent product. So even when a drug</p>	<p style="text-align: right;">Page 570</p> <p>1 generics? 2 MS. BROOKER: Objection, form. 3 A. Yes. That appears to be true. 4 Q. Did you take a look and compare them to the 5 trend in prices for the competing brands? 6 A. Again, for the opinions I've offered in my 7 report that wasn't necessary. 8 Q. Okay. So you did not compare the Dey and 9 Roxane products with the prices of the competing 10 brands? That's outside the scope of what you were 11 asked to do? 12 A. I probably have looked at that, but not in 13 the scope and not related to this report and I don't 14 recall what was there as -- I actually have studied 15 every brand product that's had generic competition 16 enter since 1980. And at some point in my career I've 17 looked at the pattern that occurred with those. But I 18 don't recall these specific products in this case. 19 And I didn't look at it in the context of this case 20 because to my knowledge there's nothing expressed in 21 my report that required that or that that was 22 necessary for.</p>

50 (Pages 567 to 570)

Schondelmeyer, Pharm.D., Ph.D., Stephen W. - Vol. II

February 26, 2009

Washington, DC

<p style="text-align: right;">Page 575</p> <p>1 for a pharmacy provider perspective.</p> <p>2 Q. Well, if a generic is trying to enter the</p> <p>3 market and the brand has a better spread, the brand</p> <p>4 might still be able to compete on price even though</p> <p>5 the generic's price may be lower, correct?</p> <p>6 MS. BROOKER: Objection, form.</p> <p>7 A. One would have -- you know, one could</p> <p>8 evaluate various scenarios that exist out there.</p> <p>9 Q. But it could happen?</p> <p>10 A. I wasn't asked to assess that here and I</p> <p>11 would have to think through the elements of what would</p> <p>12 be appropriate. And it's not something I'd attempt to</p> <p>13 design sitting here today.</p> <p>14 Q. Well, if for instance a Dey marketing</p> <p>15 executive or someone with knowledge from Dey came in</p> <p>16 and explained that they looked at the existing brand</p> <p>17 spread and saw that the brand would be able to compete</p> <p>18 with them using the spreads subsidized by Medicaid</p> <p>19 payments, is that a legitimate thing for those</p> <p>20 officials to take into account when they set their</p> <p>21 prices?</p> <p>22 MS. BROOKER: Objection, form.</p>	<p style="text-align: right;">Page 577</p> <p>1 comments they made about various aspects, including</p> <p>2 some comments that they were getting killed on the</p> <p>3 spread some somebody else or needed to, you know --</p> <p>4 they wanted to adjust their pricing because of that or</p> <p>5 something.</p> <p>6 Q. You saw evidence that Dey was getting hurt</p> <p>7 by its competitors on the spread? Is that what you</p> <p>8 mean?</p> <p>9 A. I saw comments of Dey personnel saying</p> <p>10 that.</p> <p>11 Q. Well, let's go back, though. The Dey</p> <p>12 evidence on why the price was set the way it was at</p> <p>13 the time it launched different drugs and the testimony</p> <p>14 of the individuals who made the decisions, did you</p> <p>15 read their testimony?</p> <p>16 MS. BROOKER: Objection, form.</p> <p>17 A. Again, whose testimony?</p> <p>18 Q. I'm asking you to tell me. I'm not going</p> <p>19 to tell you.</p> <p>20 A. No. You asked me the question. I didn't</p> <p>21 hear you question --</p> <p>22 Q. I noticed in your report you had a few</p>
<p style="text-align: right;">Page 576</p> <p>1 A. Is it legitimate?</p> <p>2 Q. Yeah.</p> <p>3 A. I think it's a factor they could take into</p> <p>4 account, realizing that they run the risk of causing</p> <p>5 Medicaid to pay more than they might otherwise pay</p> <p>6 that may lead to other issues legally or morally.</p> <p>7 Q. But if their price was lower in any case</p> <p>8 Medicaid is still going to pay less than they're</p> <p>9 paying for the brand, right?</p> <p>10 MS. BROOKER: Objection, form.</p> <p>11 A. I can't answer that without details of</p> <p>12 prices in both cases, because it doesn't necessarily</p> <p>13 assure that it will be a lower price.</p> <p>14 Q. All right. Well, did you examine the Dey</p> <p>15 review of these manufacturer processing and things</p> <p>16 like that?</p> <p>17 A. Manufacturer what?</p> <p>18 Q. Did you examine the decision-making of the</p> <p>19 Dey people?</p> <p>20 A. I did read --</p> <p>21 MS. BROOKER: Objection, form.</p> <p>22 A. I did read testimony of Dey personnel and</p>	<p style="text-align: right;">Page 578</p> <p>1 launch documents, correct?</p> <p>2 A. Okay.</p> <p>3 Q. Okay you understand what I said or okay I'm</p> <p>4 correct?</p> <p>5 A. I cite in here reports from Dey that</p> <p>6 included launch documents, I believe.</p> <p>7 Q. All right. Now, my question is did you</p> <p>8 review the testimony of the Dey people who were</p> <p>9 actually working on the launch and making the</p> <p>10 decisions?</p> <p>11 MS. BROOKER: Objection, form.</p> <p>12 A. I reviewed testimony I had available to me.</p> <p>13 Q. Well, whose testimony did you review? Give</p> <p>14 me the names of the individuals that discussed the</p> <p>15 different launches of the Dey products. Tell me whose</p> <p>16 testimony you reviewed.</p> <p>17 A. Sitting here I can't tell you all of that.</p> <p>18 Q. I don't see their names in your report.</p> <p>19 Did you list their names in the report?</p> <p>20 MS. BROOKER: Objection, form.</p> <p>21 A. I don't know if their names are listed in</p> <p>22 the report.</p>

52 (Pages 575 to 578)

<p style="text-align: right;">Page 579</p> <p>1 Q. Did you make notes of what they said?</p> <p>2 A. I did not take notes, no.</p> <p>3 Q. Okay. Well, then as best you can tell me</p> <p>4 the sum and substance of the Dey testimony that you</p> <p>5 reviewed that discussed why the different price points</p> <p>6 were selected.</p> <p>7 A. I recall one or two things in my report</p> <p>8 that describe that that I could refer to.</p> <p>9 Q. I'm not talking about the documents. I</p> <p>10 understand you've cited documents. I'm specifically</p> <p>11 asking about the testimony you read, what people said.</p> <p>12 Tell me as best you can what testimony you recall</p> <p>13 where the Dey pricing was set. And start with telling</p> <p>14 me whose it was.</p> <p>15 A. I don't recall the details of the</p> <p>16 depositions without looking back at them. I read</p> <p>17 hundreds of thousands of pages in this over all these</p> <p>18 three cases the last year. And I can't sit here and</p> <p>19 quote back to you the specifics.</p> <p>20 Q. Well, you didn't make any notes either, did</p> <p>21 you?</p> <p>22 A. I don't make notes typically. I pull</p>	<p style="text-align: right;">Page 581</p> <p>1 A. That's an over-simplification, but yes.</p> <p>2 Q. Okay. And as you sit here today you cannot</p> <p>3 tell me the names of the persons whose testimony you</p> <p>4 relied on?</p> <p>5 MS. BROOKER: Objection, form.</p> <p>6 A. Not from memory. I list in the disclosure</p> <p>7 testimonies that I had available to me and reviewed.</p> <p>8 Q. Okay. Well, if we showed the names of the</p> <p>9 people in the disclosures would you be able to go</p> <p>10 through and tell me what each of them said about the</p> <p>11 launch of each Dey product? Do you think your memory</p> <p>12 is that good?</p> <p>13 A. No. I can't repeat verbatim deposition</p> <p>14 testimonies. I don't memorize things at that level.</p> <p>15 Q. Well, not verbatim, but the sum and</p> <p>16 substance of what they said.</p> <p>17 A. I probably can't quote it at that level</p> <p>18 either.</p> <p>19 Q. Would you even be able to tell me which</p> <p>20 official was involved in which product?</p> <p>21 A. I could line that up. Given time I could</p> <p>22 go through and organize that.</p>
<p style="text-align: right;">Page 580</p> <p>1 together the documents, review them at a specific</p> <p>2 point in time, assimilate and write the report. And</p> <p>3 then I set aside those documents and move on to</p> <p>4 another project where I review similar large amounts</p> <p>5 of data.</p> <p>6 Q. So when you sat down to formulate your</p> <p>7 opinions about Dey's pricing you didn't have access to</p> <p>8 any notes you made of Dey testimony, correct?</p> <p>9 A. I had access to Dey testimony. I don't</p> <p>10 make notes.</p> <p>11 Q. Well, you had stacks of the I guess</p> <p>12 transcripts stacked up? You had that?</p> <p>13 A. Yes.</p> <p>14 Q. But you didn't make any notes, right?</p> <p>15 A. You've asked that several times. I don't</p> <p>16 make notes.</p> <p>17 Q. You didn't highlight the transcripts or put</p> <p>18 Post-Its in there or anything like that?</p> <p>19 A. I typically don't, no.</p> <p>20 Q. So basically you read this stuff, you came</p> <p>21 to your conclusion and you put it in your report,</p> <p>22 right?</p>	<p style="text-align: right;">Page 582</p> <p>1 Q. But you'd have to go back to the</p> <p>2 transcripts to do that, right?</p> <p>3 A. I'd have to go back to the source I used</p> <p>4 the first time to determine that. But again, I do a</p> <p>5 project, I analyze it carefully and drew conclusions</p> <p>6 and reported those and then set those aside and moved</p> <p>7 on to a number of other projects.</p> <p>8 Q. You mentioned there was another Dey case.</p> <p>9 Can you tell me how many Dey transcripts you read?</p> <p>10 A. I don't recall off the top of my head, no.</p> <p>11 Q. Did you read any transcripts of any Roxane</p> <p>12 people?</p> <p>13 A. I did read Roxane transcripts, yes.</p> <p>14 Q. How many of them did you read?</p> <p>15 A. I don't recall.</p> <p>16 Q. Can you give me the name of a single</p> <p>17 witness from either Dey or Roxane that you remember</p> <p>18 that you read the transcript of?</p> <p>19 A. They would be ones listed in the disclosure</p> <p>20 again.</p> <p>21 Q. You spent 40 to 70 hours planning for the</p> <p>22 deposition today and you still can't remember the name</p>

53 (Pages 579 to 582)

<p style="text-align: right;">Page 587</p> <p>1 true and I wanted to clarify that.</p> <p>2 Q. What made you want to read Ms. Selenati's</p> <p>3 deposition?</p> <p>4 A. I believe I had seen their names in other</p> <p>5 documents that related to the case that appeared to be</p> <p>6 useful and important documents in terms of</p> <p>7 understanding what was going on.</p> <p>8 Q. So you were reading the depositions of</p> <p>9 everyone whose name was on a document or just some</p> <p>10 or --</p> <p>11 MS. BROOKER: Objection, form.</p> <p>12 Q. -- how did you go about making that cut?</p> <p>13 A. Again, I had documents in the case from</p> <p>14 Dey, corporate documents internally.</p> <p>15 Q. Where did you get those?</p> <p>16 A. These were individual -- those were also</p> <p>17 posted on the website of documents related to this</p> <p>18 case that were produced and that have been disclosed</p> <p>19 to you.</p> <p>20 Q. Right. And how did you select those 16</p> <p>21 documents or 18 documents that are in your report?</p> <p>22 A. Well, first I didn't select those 16 or 18.</p>	<p style="text-align: right;">Page 589</p> <p>1 AFTERNOON SESSION</p> <p>2 (2:05 p.m.)</p> <p>3 * * * * *</p> <p>4 Whereupon,</p> <p>5 STEPHEN W. SCHONDELMAYER, PHARM.D., PH.D.,</p> <p>6 the witness testifying at the time of</p> <p>7 recess, having been previously duly sworn,</p> <p>8 was further examined and testified as</p> <p>9 follows.</p> <p>10 * * * * *</p> <p>11 EXAMINATION RESUMED BY COUNSEL FOR DEY,</p> <p>12 INC., DEY, L.P. AND MYLAN</p> <p>13 THE VIDEOGRAPHER: This is the beginning of</p> <p>14 tape 3 in the deposition of Dr. Schondelmeyer. On the</p> <p>15 record at 2:05.</p> <p>16 BY MR. MERKL:</p> <p>17 Q. When last we left you were alone with your</p> <p>18 computer and 3 million Dey documents.</p> <p>19 MR. BREEN: 3,000,040, I think.</p> <p>20 MR. MERKL: 3,000,040.</p> <p>21 BY MR. MERKL:</p> <p>22 Q. Now, I believe 18 documents make it to your</p>
<p style="text-align: right;">Page 588</p> <p>1 Q. Okay.</p> <p>2 A. I asked for documents from the lawyers in</p> <p>3 the indication for documents related to marketing, to</p> <p>4 reimbursement, documents related to pricing.</p> <p>5 Q. Let me -- we have 3.3 million pages of</p> <p>6 documents produced in this case. It's fair to say you</p> <p>7 didn't look at all those, right?</p> <p>8 MS. BROOKER: Objection, form.</p> <p>9 Q. True?</p> <p>10 A. It would be fair to say I didn't look at</p> <p>11 3.X million documents.</p> <p>12 MR. MERKL: The tape is out. We've got to</p> <p>13 stop.</p> <p>14 THE VIDEOGRAPHER: This is the end of tape</p> <p>15 2. Off the record at 1:05.</p> <p>16 (Whereupon, at 1:05 p.m. a lunch recess was</p> <p>17 taken.)</p> <p>18</p> <p>19</p> <p>20</p> <p>21</p> <p>22</p>	<p style="text-align: right;">Page 590</p> <p>1 report; is that correct?</p> <p>2 A. I didn't count them. I can't tell you how</p> <p>3 many it is.</p> <p>4 Q. Well, how did you get from 3 million</p> <p>5 documents to the documents that are in your report?</p> <p>6 What did you do?</p> <p>7 A. I'm not sure the 3 million had been fully</p> <p>8 disclosed to me either and I didn't ask to nor want to</p> <p>9 nor expect to read all of those. I did ask for</p> <p>10 documents, documents related to marketing, related to</p> <p>11 pricing, related to reimbursement, third party</p> <p>12 reimbursement and things that incorporated any of</p> <p>13 those aspects in other documents such as sales or</p> <p>14 training or other aspects that might have addressed</p> <p>15 reimbursement or marketing, pricing issues.</p> <p>16 Q. Well, did you have access to the complete</p> <p>17 Dey document database?</p> <p>18 A. If I could have -- I could have requested</p> <p>19 that. I felt -- nobody told me I couldn't have.</p> <p>20 Q. Did you do that?</p> <p>21 A. No, I did not, because I didn't plan on</p> <p>22 reading 3 million pages.</p>

Schondelmeyer, Pharm.D., Ph.D., Stephen W. - Vol. II

Washington, DC

February 26, 2009

<p style="text-align: right;">Page 595</p> <p>1 A. I did not.</p> <p>2 MS. BROOKER: Objection. Dr. Perri.</p> <p>3 A. I did not have any discussion with Dr.</p> <p>4 Perri in relation to this case.</p> <p>5 Q. Were either Drs. Perri or Duggan present</p> <p>6 while you were discussing your role in the case with</p> <p>7 the Justice Department team?</p> <p>8 A. No.</p> <p>9 Q. And it's in one of these meetings that the</p> <p>10 subject of which documents to look at came up at?</p> <p>11 MS. BROOKER: Objection, form.</p> <p>12 A. Early on in the case at a meeting reviewing</p> <p>13 the case reviewing their complaint I did ask for</p> <p>14 documents and they produced those. As I worked on and</p> <p>15 had additional interests in other documents I would</p> <p>16 relay a communication if there were things I wanted to</p> <p>17 see. They would identify those if they existed within</p> <p>18 the documents that had been produced.</p> <p>19 Q. Well, let's start at this first meeting</p> <p>20 where you told me you asked for marketing documents,</p> <p>21 pricing documents, third party reimbursement documents</p> <p>22 and some sales and training things. You asked for</p>	<p style="text-align: right;">Page 597</p> <p>1 single Dey marketing document?</p> <p>2 A. I didn't word it exactly that way.</p> <p>3 Q. How did you word it?</p> <p>4 A. I would like to see documents related to</p> <p>5 marketing, documents related to reimbursement,</p> <p>6 documents related to pricing and documents related to</p> <p>7 sales and training that addressed marketing and</p> <p>8 pricing issues.</p> <p>9 Q. So you're the expert retained by --</p> <p>10 A. So I asked like is there a marketing plan,</p> <p>11 are there product launch plans, is there a pricing</p> <p>12 grid, is there either a business development report or</p> <p>13 document, are there product -- oh, sometimes you call</p> <p>14 them product profiles, product status reports, annual</p> <p>15 reports on various products and related documents of</p> <p>16 that type as well.</p> <p>17 Q. So you asked for all that stuff?</p> <p>18 A. I asked for documents of that type, yes.</p> <p>19 Q. Okay. Did you ask for it for the entire</p> <p>20 period of time from 1992 to 2007?</p> <p>21 A. Yes.</p> <p>22 Q. Okay.</p>
<p style="text-align: right;">Page 596</p> <p>1 those at the outset?</p> <p>2 A. Sales and training things related to</p> <p>3 reimbursement or pricing and marketing of those.</p> <p>4 Q. What individual did you ask for those</p> <p>5 documents? Who specifically did you ask to give them</p> <p>6 to you?</p> <p>7 A. I think it was in the room with the three</p> <p>8 lawyers and I left it up to whoever among the lawyers</p> <p>9 had control or access to the documents that had been</p> <p>10 produced.</p> <p>11 Q. What exactly did you tell them you wanted</p> <p>12 with respect to marketing documents?</p> <p>13 A. I think basically what I've told you is the</p> <p>14 nature of what I described that I wanted.</p> <p>15 Q. No. I mean, did you say, look, I need to</p> <p>16 see every single Dey marketing document for the drugs</p> <p>17 in the case or did you say I want to see the marketing</p> <p>18 the spread documents or what kind of marketing</p> <p>19 documents did you ask them for?</p> <p>20 A. I think it was a fairly broad request. It</p> <p>21 wasn't overly specific.</p> <p>22 Q. Well, how broad? Did you ask to see every</p>	<p style="text-align: right;">Page 598</p> <p>1 A. In terms of what was available. I, again,</p> <p>2 didn't know all of what had been produced.</p> <p>3 Q. And sticking with the marketing stuff, when</p> <p>4 you asked for marketing plans did you say though you</p> <p>5 wanted all the marketing plans, all the pricing grids</p> <p>6 or all the development documents, or did you just</p> <p>7 leave it to counsel to decide which ones you would</p> <p>8 get?</p> <p>9 A. I believe I asked for marketing documents</p> <p>10 in a broad sense.</p> <p>11 Q. When you say in a broad sense, what do you</p> <p>12 mean? Did you ask for all the marketing documents for</p> <p>13 each drug for a 15-year period or didn't you?</p> <p>14 A. I said I would like marketing documents</p> <p>15 over the time period involved in the case.</p> <p>16 Q. Well, did you get marketing documents for</p> <p>17 each of the three drugs for a 15-year period?</p> <p>18 A. I got some that appeared to be to be across</p> <p>19 that period. I'm not sure that there existed</p> <p>20 documents for each and every year for each and every</p> <p>21 drug during that time period because the products</p> <p>22 weren't all on the market during that entire time</p>

57 (Pages 595 to 598)

Schondelmeyer, Pharm.D., Ph.D., Stephen W. - Vol. II

February 26, 2009

Washington, DC

<p style="text-align: right;">Page 599</p> <p>1 period. So --</p> <p>2 Q. You're telling me albuterol wasn't on the</p> <p>3 market from 1992 to --</p> <p>4 A. Cromolyn, ipratropium were not.</p> <p>5 Q. They weren't?</p> <p>6 A. From 1992. I don't believe so. I'm not</p> <p>7 sure.</p> <p>8 Q. How about from '95 onward?</p> <p>9 A. They were launch products.</p> <p>10 MR. BREEN: Excuse me. I'm having a hard</p> <p>11 time following again. You guys are starting to talk</p> <p>12 over each other. So I'd request that the witness</p> <p>13 allow a question to be asked and then answer it so</p> <p>14 that we can get a thought in or an objection in</p> <p>15 edgewise. I'd appreciate that. Thank you.</p> <p>16 BY MR. MERKL:</p> <p>17 Q. So to go back to these marketing documents,</p> <p>18 how do you know that you got all the marketing</p> <p>19 documents that are relevant to your opinion?</p> <p>20 A. I asked for marketing documents as I've</p> <p>21 described to you several times this morning. And I</p> <p>22 described that, asked the lawyers to provide that and</p>	<p style="text-align: right;">Page 601</p> <p>1 A. I asked about testimony of people involved</p> <p>2 in the documents that were produced that we had. And</p> <p>3 I believe I had depositions for most of the people</p> <p>4 that were involved with the documents produced from my</p> <p>5 earlier requests.</p> <p>6 Q. But you didn't read them all, did you?</p> <p>7 A. Didn't read all of what?</p> <p>8 Q. All of the depositions, did you?</p> <p>9 A. I didn't read all of the depositions taken</p> <p>10 in the case.</p> <p>11 Q. Which ones did you read?</p> <p>12 A. Well, I told you earlier I can't remember</p> <p>13 all that I read. We went through some. Mark Pope.</p> <p>14 Helen Selenati. I remember reading some from Charles</p> <p>15 Rice. I'd have to look back --</p> <p>16 Q. Tell me --</p> <p>17 A. Can I finish my answer?</p> <p>18 Q. Go ahead.</p> <p>19 A. You're jumping in before I finish my</p> <p>20 answer.</p> <p>21 I mentioned Robert Mozak. I read documents</p> <p>22 from him. Maybe Ross Uhl.</p>
<p style="text-align: right;">Page 600</p> <p>1 I assume that they did so.</p> <p>2 Q. So you're relying on the lawyers to pick</p> <p>3 the documents for you to review?</p> <p>4 A. That's not a true statement. I did direct</p> <p>5 them the types of information I wanted and I did</p> <p>6 assume that they would do that respectfully and within</p> <p>7 the context of my request.</p> <p>8 Q. But you don't know if they really gave you</p> <p>9 all the relevant Dey marketing documents, do you?</p> <p>10 MS. BROOKER: Objection, form.</p> <p>11 A. I did not review all of the, whatever it</p> <p>12 is, 3 million pages that existed.</p> <p>13 Q. What did you do to make sure that you got</p> <p>14 all the documents for marketing?</p> <p>15 A. I asked for the documents as I described to</p> <p>16 you. I assume and expect that those lawyers complied</p> <p>17 with what I asked and I used those documents. There</p> <p>18 were occasions where I would ask is there a document</p> <p>19 about X or Y and if it was they would find that and</p> <p>20 produce it.</p> <p>21 Q. Did you ask them for any testimony of</p> <p>22 people explaining the documents?</p>	<p style="text-align: right;">Page 602</p> <p>1 Q. Maybe or are you sure?</p> <p>2 A. I don't remember. I'd have to go back and</p> <p>3 look. I remember the name Ross Uhl. I had those</p> <p>4 documents. I probably read portions of those. And I</p> <p>5 don't remember without looking back how much I would</p> <p>6 have read of that.</p> <p>7 Q. Now having refreshed your --</p> <p>8 A. I'm not finished.</p> <p>9 Q. Okay. Have you got some more?</p> <p>10 A. Those are the ones I recall now, but again,</p> <p>11 I wouldn't say that's all that I read. These are the</p> <p>12 ones that I recall sitting here today thinking back</p> <p>13 about what I've read over the last six months.</p> <p>14 Q. And what was the sum and substance of their</p> <p>15 testimony concerning the Dey marketing plans?</p> <p>16 MS. BROOKER: Objection, form.</p> <p>17 MR. BREEN: Objection, form.</p> <p>18 A. My report describes the elements that I</p> <p>19 thought were relevant to my opinions and I've</p> <p>20 documented those in my report and we could refer to</p> <p>21 those. If you have a specific point you want to refer</p> <p>22 to I'd be glad to discuss that.</p>

58 (Pages 599 to 602)

<p style="text-align: right;">Page 603</p> <p>1 Q. I don't see any testimony quoted in your 2 report. I see some documents. My question is apart 3 from the documents that I can see in your report what 4 testimony did you refer to to come to your 5 conclusions -- 6 MS. BROOKER: Objection, form. 7 Q. -- if any? 8 A. Well, I think it was helpful to read the 9 depositions of the individuals involved. I think the 10 documents themselves in the way they were quoted in my 11 report were sufficient to make the opinions that I've 12 arrived at. 13 Q. What did Mr. Pope say about the Dey 14 marketing plans? 15 A. I don't remember specifically what was in 16 those depositions, all that I read, as I've said. 17 Q. What did Mr. Mozak say about the albuterol 18 product launch? 19 A. I'd have to go back and look. I don't 20 recall. 21 Q. Okay. Can you tell me specifically what 22 any of these witnesses said about the spread?</p>	<p style="text-align: right;">Page 605</p> <p>1 sales material did you ask for? What exactly? 2 MR. BREEN: Objection, form. 3 A. Again, I believe I've told you the nature 4 of how I requested this earlier. 5 Q. Now. You've told me how, I agree, and 6 you've told me what marketing material you asked for. 7 Now I would like to turn to the sales material. What 8 sales material did you ask for? 9 A. Sales material that involved addressing 10 price and the spread. 11 Q. What does that mean? Did you ask for sales 12 statistics by quarter? Did you ask for complete sales 13 reports for all the drugs? Did you ask sales reports 14 that only talk about marketing the spread? Which is 15 it? 16 MS. BROOKER: Objection, form. 17 MR. BREEN: Objection, form. 18 A. Well, I didn't ask in those same ways. I 19 asked in a broad sense. In my mind sales material 20 that contains information related to price or the 21 spread or sales and training material includes those, 22 would encompass everything that you asked, and that's</p>
<p style="text-align: right;">Page 604</p> <p>1 MS. BROOKER: Objection, form. 2 A. I don't recall specifics as we sit here 3 today, as I've said. I did read through parts of all 4 of those depositions. I did read through documents. 5 I feel that everything in my report shows a basis for 6 that within the report itself. And the positions in 7 my report refer to Dey documents when appropriate and 8 that was all that was necessary to arrive at the 9 conclusions that I did. 10 Q. Well, which witness' testimony did you 11 consider in arriving at your conclusion that Dey 12 inflated prices? Which witness' testimony supports 13 that conclusion? 14 MR. BREEN: Objection, form. 15 A. Well, I didn't say that any of these were 16 based on witness' testimony necessarily. It may or 17 may not have been. I'd be glad to -- show me where I 18 say that in my report. 19 Q. Well, you don't say you relied on a 20 witness. That's my question. 21 MR. BREEN: Objection, form. 22 Q. Okay. Now, you say sales. What kind of</p>	<p style="text-align: right;">Page 606</p> <p>1 what I expected. 2 Q. Did you ask to see sales documents that 3 showed that no one was marketing the spread? Did you 4 ask for that? 5 MR. BREEN: Objection, form. 6 A. I don't understand your question. 7 Q. Did you ask them to show you any documents 8 that showed Dey was not marketing the spread? Did you 9 ask them to give you those kinds of documents? 10 MR. BREEN: Objection, form. 11 A. I asked for documents that involved prices 12 or the spread or discussions of those with respect to 13 marketing, sales training. If they had documents that 14 showed that they weren't doing so that would have been 15 produced also. 16 Q. Well, how do you know they would have given 17 you them? 18 MR. BREEN: Objection, form. 19 Q. Let me withdraw the question. What did you 20 do to make sure that they had given you all the sales 21 documents? 22 MS. BROOKER: Objection, form.</p>

Schondelmeyer, Pharm.D., Ph.D., Stephen W. - Vol. II

Washington, DC

February 26, 2009

<p style="text-align: right;">Page 607</p> <p>1 A. I've described what I asked for and how I</p> <p>2 asked for it in general. And I described that I did</p> <p>3 assume a measure of trust that the lawyers would give</p> <p>4 me the documents that fit within the scope of what I</p> <p>5 asked. And I did not assess all 3 million documents</p> <p>6 to make sure they didn't leave one out.</p> <p>7 Q. Did you review any document indices?</p> <p>8 A. No. I did not ask for that. I did not</p> <p>9 review that.</p> <p>10 Q. Did you review any sets of files, for</p> <p>11 instance, all the files from the marketing department</p> <p>12 or the sales department?</p> <p>13 MS. BROOKER: Objection, form.</p> <p>14 A. No. I did not ask for that or review that.</p> <p>15 Q. Well, you're a scholar, right? You</p> <p>16 consider yourself a scholar? This is your area of</p> <p>17 expertise?</p> <p>18 MS. BROOKER: Objection, form.</p> <p>19 MR. BREEN: Objection, form.</p> <p>20 Q. Am I correct?</p> <p>21 A. What is your question?</p> <p>22 Q. You're a scholar, correct?</p>	<p style="text-align: right;">Page 609</p> <p>1 MR. BREEN: Objection, form.</p> <p>2 A. I don't understand what you're asking.</p> <p>3 Q. Okay. I'll try it again.</p> <p>4 A. I've described what I asked. I was aware</p> <p>5 that there were far more documents than I could read</p> <p>6 or screen or be aware of. I asked for types of</p> <p>7 documents and I received those. I felt like the</p> <p>8 production that I got contained the types of documents</p> <p>9 that I would have expected to see. And I reviewed</p> <p>10 those and used among those the ones that were relevant</p> <p>11 to the opinions that I formed. And I cited specific</p> <p>12 ones in the report that I relied upon.</p> <p>13 Q. You have a Ph.D.?</p> <p>14 A. Yes, I do.</p> <p>15 Q. And are there any scholarly standards for</p> <p>16 writings and things that you have to follow as a</p> <p>17 Ph.D.?</p> <p>18 A. I've never seen anything published of that</p> <p>19 nature, no.</p> <p>20 Q. Well, are there professional standards that</p> <p>21 a fellow scholar would expect you to follow in a peer</p> <p>22 reviewed work or something of that nature?</p>
<p style="text-align: right;">Page 608</p> <p>1 A. I'm a scholar, yes.</p> <p>2 Q. As a scholar when you're evaluating</p> <p>3 evidence in your research isn't it part of your</p> <p>4 discipline to check things that people tell you?</p> <p>5 A. It is. And I felt -- within the domain of</p> <p>6 the area that I work in in terms of pharmaceutical</p> <p>7 prices and documents, I do that. I know how to do</p> <p>8 that very well. I used the usual care that I use.</p> <p>9 I've been an expert about 60 times now in cases and</p> <p>10 I've used the same process in getting documents in</p> <p>11 arriving at conclusions in this case as I do in other</p> <p>12 cases.</p> <p>13 And I feel it's been done in an appropriate</p> <p>14 way and in a way that is sufficient to arrive at the</p> <p>15 conclusions in the reports that I developed. And I've</p> <p>16 used a similar process here and I feel like it was</p> <p>17 done in a scholarly way.</p> <p>18 Q. So you're using your usual expert witness</p> <p>19 standard? Is that what you mean?</p> <p>20 MR. BREEN: Objection, form.</p> <p>21 Q. You're testifying expert witness standard?</p> <p>22 That's the standard used here?</p>	<p style="text-align: right;">Page 610</p> <p>1 A. I do peer reviewed work and evaluate things</p> <p>2 based on my knowledge and experience and background.</p> <p>3 And that's what I applied in this case.</p> <p>4 Q. Well, I'm asking which of those standards</p> <p>5 in terms of checking data did you apply in this case?</p> <p>6 How did you check your data?</p> <p>7 A. I believe I've been asked that and answered</p> <p>8 that several times now. I would be glad to repeat the</p> <p>9 same answer.</p> <p>10 Q. Well, you told me how you got your</p> <p>11 documents. You didn't tell me how you checked to make</p> <p>12 sure that you got all of the relevant documents.</p> <p>13 MS. BROOKER: Objection, form.</p> <p>14 Q. What did you check to make sure that your</p> <p>15 attorneys gave you everything relevant?</p> <p>16 MS. BROOKER: Objection, form.</p> <p>17 A. I believe I've been asked that and answered</p> <p>18 that. I'd be glad to repeat the same answers.</p> <p>19 Q. When you asked for the documents had you</p> <p>20 read the complaint?</p> <p>21 A. I believe I had, yes.</p> <p>22 Q. Okay. So you knew that the government and</p>

60 (Pages 607 to 610)

<p style="text-align: right;">Page 611</p> <p>1 the people who retained you were suing the</p> <p>2 manufacturer for a lot of money?</p> <p>3 MS. BROOKER: Objection, form.</p> <p>4 A. I don't know what you mean by "a lot of</p> <p>5 money." I knew that there was an allegation and a</p> <p>6 complaint.</p> <p>7 Q. You read the complaint, right?</p> <p>8 A. Yes.</p> <p>9 Q. Didn't you think that the government was</p> <p>10 suing for millions of dollars?</p> <p>11 A. I didn't attempt to do a quantitative</p> <p>12 assessment at that point.</p> <p>13 Q. I'm not asking you if you did a</p> <p>14 quantitative assessment. I'm asking you as even a</p> <p>15 layperson, having read that complaint did you get the</p> <p>16 impression that the government was suing for millions</p> <p>17 of dollars?</p> <p>18 MS. BROOKER: Objection, form.</p> <p>19 A. I read the complaint and took it at face</p> <p>20 value and realized it was a dispute between the</p> <p>21 government and a drug company over issues relating to</p> <p>22 price reporting in the marketplace.</p>	<p style="text-align: right;">Page 613</p> <p>1 ask a litigant from one side to pick the only evidence</p> <p>2 he's going to rely on?</p> <p>3 MS. BROOKER: Objection, form.</p> <p>4 A. You've mischaracterized what happened. I</p> <p>5 didn't ask them to pick the only evidence I relied</p> <p>6 upon. There were things I brought to this that are</p> <p>7 cited to my report that I brought to the table that</p> <p>8 they didn't. So I did bring in other information and</p> <p>9 evidence that didn't come through that. You've</p> <p>10 mischaracterized what I've been describing.</p> <p>11 Q. What evidence did you bring in that related</p> <p>12 directly to the conduct of Dey and Roxane?</p> <p>13 A. Related to my report, the broad conduct of</p> <p>14 the marketplace, I brought in things such as the NPC</p> <p>15 Medicaid books.</p> <p>16 Q. No. That's not my question.</p> <p>17 MS. BROOKER: Objection, form.</p> <p>18 A. In my report there are documents in my</p> <p>19 report that speak to the government's statutes and</p> <p>20 policies and regulations of Medicaid that I consider</p> <p>21 to be evidence in this case.</p> <p>22 Q. My question is limited to the conduct you</p>
<p style="text-align: right;">Page 612</p> <p>1 Q. Did you think it was a big case?</p> <p>2 MS. BROOKER: Objection, form.</p> <p>3 A. Big by what standard? Not -- I've had</p> <p>4 other cases that have been billions of dollars. It</p> <p>5 didn't seem to reach that standard. But I -- it's</p> <p>6 millions? Perhaps. I didn't think in dollar terms</p> <p>7 what's the value of this. I look at what are the</p> <p>8 issues and are the issues and expertise that I have --</p> <p>9 is my expertise such that I could help provide</p> <p>10 information to the judge or jury that might be useful</p> <p>11 in this case.</p> <p>12 Q. You realize the government is an interested</p> <p>13 party in the case, correct?</p> <p>14 A. Yes. They're a named plaintiff.</p> <p>15 Q. So don't you think it somewhat unreasonable</p> <p>16 for an expert who's supposed to -- do you believe</p> <p>17 you're supposed to give an objective opinion?</p> <p>18 MS. BROOKER: Objection, form.</p> <p>19 A. I do give an objective and independent</p> <p>20 opinion, yes.</p> <p>21 Q. Well, do you think it's reasonable for</p> <p>22 someone charged with forming an objective opinion to</p>	<p style="text-align: right;">Page 614</p> <p>1 ascribed to Dey and Roxane. All the evidence you base</p> <p>2 your conclusions against Dey and Roxane, all the</p> <p>3 documents that you cite in your report, were basically</p> <p>4 documents cherry picked out by counsel for Plaintiff</p> <p>5 and given to you, correct?</p> <p>6 MS. BROOKER: Objection, form.</p> <p>7 A. I don't view them as cherry picked. I</p> <p>8 asked categories of broad categories and I would</p> <p>9 occasionally ask is there anything else in this area</p> <p>10 or not. And they would provide those if there was</p> <p>11 such.</p> <p>12 Q. So you would basically ask for a -- you</p> <p>13 would say give me all the marketing documents and you</p> <p>14 leave it to Mr. Breen and his colleagues to pick out</p> <p>15 which ones you should look at?</p> <p>16 MS. BROOKER: Objection, form.</p> <p>17 Q. That's what happened?</p> <p>18 A. I asked for a broad set of documents, as</p> <p>19 I've described. I've been asked that and answered it</p> <p>20 several times. I'd be glad to repeat what I've been</p> <p>21 saying.</p> <p>22 Q. Why is it your report doesn't refer to any</p>

<p style="text-align: right;">Page 615</p> <p>1 documents prepared after 2000?</p> <p>2 A. What do you mean?</p> <p>3 Q. Your document, when you talk about Dey's</p> <p>4 conduct, you don't really reference any documents from</p> <p>5 Dey after the year 2000. Why is that?</p> <p>6 A. I don't know. I feel like the documents</p> <p>7 referred to represent and support the opinions I've</p> <p>8 offered and do so appropriately.</p> <p>9 Q. Well, what evidence did you refer to that</p> <p>10 you can tell me you looked at that inform your</p> <p>11 opinions as to what Dey was doing during the years,</p> <p>12 say, 2001 through 2006? What evidence are you basing</p> <p>13 those conclusions on?</p> <p>14 MR. BREEN: Objection, form.</p> <p>15 A. Again, if you could show me in my report</p> <p>16 where I refer to something that reflects Dey's conduct</p> <p>17 between 2001 and the present, I would be glad to</p> <p>18 review that and attempt to answer your question.</p> <p>19 Q. I'm sorry. I thought your opinion as to</p> <p>20 Dey's conduct was from '92 to the present. If you're</p> <p>21 telling me what Dey did after 2001 is outside the</p> <p>22 scope of your report, then we have nothing more to</p>	<p style="text-align: right;">Page 617</p> <p>1 Q. Is it your opinion Dey was marketing the</p> <p>2 spread after 2000?</p> <p>3 A. I need to review -- refer to my report. I</p> <p>4 don't remember everything that I've got in my report</p> <p>5 at this point.</p> <p>6 Q. So as you sit here today you don't know</p> <p>7 whether if it's your opinion whether Dey marketed the</p> <p>8 spread after 2000? You can't answer that without</p> <p>9 reading your report?</p> <p>10 A. I can answer that my report as I have</p> <p>11 prepared is my opinion. It represents those opinions</p> <p>12 and I can't quote to you verbatim the details of this.</p> <p>13 But I'd be glad to review any section of this you want</p> <p>14 to talk about.</p> <p>15 Q. Well, you spent between 40 to 70 hours</p> <p>16 preparing for your deposition here today and am I</p> <p>17 correct that you can't tell me whether or not you</p> <p>18 conclude Dey marketed the spread after the year 2000?</p> <p>19 MR. BREEN: Objection, form.</p> <p>20 A. I can't tell you sitting here today. I</p> <p>21 reviewed a number of documents, most of those were the</p> <p>22 broad spectrum of documents involved with Abbott, Dey,</p>
<p style="text-align: right;">Page 616</p> <p>1 talk about. I'll move on.</p> <p>2 MS. BROOKER: Objection, form.</p> <p>3 A. No. I'm not telling you that. You've</p> <p>4 mischaracterized it. There are aspects of my report</p> <p>5 that talk about Medicaid and various things that</p> <p>6 encompass the entire time period. And I refer to</p> <p>7 documents --</p> <p>8 Q. No. We're just talking about Dey now.</p> <p>9 A. The Dey -- may I finish? May I finish?</p> <p>10 Q. Go ahead.</p> <p>11 A. The Dey section -- there is a section on</p> <p>12 here about Dey conduct and it reports the information</p> <p>13 on Dey conduct that I felt was relevant to the report</p> <p>14 and what I was asked to address in this report and</p> <p>15 I've addressed those things. And I feel like the</p> <p>16 documents cited were sufficient to support that.</p> <p>17 Q. Let me try it this way. What conduct did</p> <p>18 you conclude that Dey engaged in after the year 2000?</p> <p>19 MS. BROOKER: Objection, form.</p> <p>20 A. I would have to refer to my report and we</p> <p>21 can review sections of that. You're welcome to ask me</p> <p>22 questions about statements in my report.</p>	<p style="text-align: right;">Page 618</p> <p>1 Roxane and Medicaid and Medicare. A wide variety of</p> <p>2 documents to review.</p> <p>3 Q. Now, your report addresses the launch of</p> <p>4 some Dey drugs, albuterol, cromolyn and ipratropium.</p> <p>5 Do you recall that part of your report?</p> <p>6 A. I do, yes.</p> <p>7 Q. All right. Now, after launch, right, say</p> <p>8 six months after launch, can you tell me what evidence</p> <p>9 you looked at to see how Dey marketed or sold its</p> <p>10 products six months after the launch of each of those</p> <p>11 products?</p> <p>12 A. There may have been -- I don't recall</p> <p>13 specifically what I looked at. I'd have to look back.</p> <p>14 There may have been comments from various of the</p> <p>15 people in the depositions related to that.</p> <p>16 Q. Now, did you review Dey's WACs for all its</p> <p>17 products that are at issue in this case? That would</p> <p>18 be ipratropium, albuterol and cromolyn. Did you</p> <p>19 review Dey's reported WACs for all those products from</p> <p>20 1992 to 2005?</p> <p>21 A. Well, there was a period in which I think</p> <p>22 Dey quit reporting WACs.</p>

62 (Pages 615 to 618)

<p style="text-align: right;">Page 619</p> <p>1 MR. MERKL: Would you read the question 2 back, please? 3 (Whereupon, the requested portion was read 4 by the reporter.) 5 BY MR. MERKL: 6 Q. Did you? 7 A. I did at the time I prepared my report, 8 yes. 9 Q. How long ago was that that you reviewed 10 those? 11 A. I don't recall. I'd have to -- 12 Q. So it might have been a year since you've 13 looked at what Dey's WACs were? 14 A. I don't believe a year. 15 Q. Six months? 16 A. Six months could be. 17 Q. Now, Dey's WACs -- let's start with 18 albuterol. After the initial launch did Dey's WAC go 19 up or did it go down for its albuterol products? 20 MR. BREEN: Objection, form. 21 A. Again, I can't quote to you the detail of 22 that. I didn't go back and review that --</p>	<p style="text-align: right;">Page 621</p> <p>1 inflated? 2 MS. BROOKER: Objection, form. 3 A. Again, I don't want to give you a new 4 opinion above and beyond what I've analyzed and 5 provided in this report. If you want to point me to a 6 statement in here I'd be glad to look at and explain 7 what that means and document it. 8 Q. You've supposedly done all this work. 9 You've spent 40 to 70 hours preparing for your 10 depositions this week, you wrote a 100 page report and 11 you can't tell me whether or not Dey's WACs went up or 12 down during the period at issue in this case? 13 MS. BROOKER: Objection, form. 14 MR. BREEN: Objection, form. 15 A. I can tell you my opinions are documented 16 in the 100 page report I've written and I'd be glad to 17 address any statement or opinion in that report that I 18 carefully developed and considered after reviewing 19 documents and data and other materials. 20 Q. Is it your opinion Dey's WACs were 21 inflated? 22 MS. BROOKER: Objection, form.</p>
<p style="text-align: right;">Page 620</p> <p>1 Q. So as you sit here today -- 2 A. -- in preparing for today. I did review 3 all of that in preparing my report. To the degree 4 that there were relevant aspects from those 5 observations and analysis, I included that in my 6 report. I'd be glad -- if you want to point me to a 7 specific position or opinion I made in my report I'd 8 be glad to address that. 9 Q. Well, is it your opinion that Dey was 10 marketing the spread? Is that your opinion? 11 MS. BROOKER: Objection, form. 12 A. My opinions are stated in my report and I 13 would refer to that report for my opinions. 14 Q. Without looking at the report can you tell 15 me is it your opinion Dey was marketing the spread? 16 MS. BROOKER: Objection, form. 17 A. I won't give you an off the cuff opinion. 18 My opinions are stated and appropriately qualified in 19 my report. And I'd refer you to that and be glad to 20 address any statement in here you'd like me to 21 explain. 22 Q. Is it your opinion Dey's WACs were</p>	<p style="text-align: right;">Page 622</p> <p>1 A. I don't want to form that new opinion as we 2 sit here today. My opinions are stated in my report 3 and if you could show me where I've made a statement 4 to that effects I'd be glad to -- 5 Q. Sir, you're the expert. You reviewed this 6 and I'm asking you did Dey inflate its WACs -- 7 MS. BROOKER: Objection, form. 8 Q. -- in your opinion? 9 A. My opinion is stated fully in my report 10 with all the appropriate qualifications. And I would 11 ask that you read that or refer to a statement in 12 there. 13 Q. Why don't you take a look at your report 14 now and see if based on your report you're able to 15 tell me whether or not Dey inflated its WACs. 16 A. I'd be glad to review the sections that 17 specifically talk to Dey's conduct, if that's what 18 you're asking. 19 Q. No. What I'm asking is what I said. If 20 you'd like the question read back, he'll read it back. 21 A. Sure. 22 (Whereupon, the requested portion was read</p>

63 (Pages 619 to 622)

<p style="text-align: right;">Page 623</p> <p>1 by the reporter.)</p> <p>2 BY MR. MERKL:</p> <p>3 Q. In your opinion.</p> <p>4 MS. BROOKER: Same objection.</p> <p>5 A. (Reading). I have quickly reviewed</p> <p>6 statements in my report. I believe there are actions</p> <p>7 of Dey as evidence the from documents within Dey that</p> <p>8 show that there was a spread that was set and that was</p> <p>9 marketed.</p> <p>10 Q. That's not my question. My question is is</p> <p>11 it your opinion that Dey inflated its WACs?</p> <p>12 MS. BROOKER: Objection, form.</p> <p>13 A. Again, you're asking me to formulate a new</p> <p>14 opinion. I would --</p> <p>15 Q. No. If that's not your opinion tell me.</p> <p>16 A. I haven't analyzed that thoroughly and I</p> <p>17 will not do so sitting here. I will respond to</p> <p>18 statements that I've already analyzed and carefully</p> <p>19 developed and documented in my report that address</p> <p>20 that issue.</p> <p>21 Q. So you don't know if Dey inflated its WACs?</p> <p>22 MS. BROOKER: Objection, form.</p>	<p style="text-align: right;">Page 625</p> <p>1 MS. BROOKER: Objection, form.</p> <p>2 A. Again, I would refer to my report and want</p> <p>3 to review the document.</p> <p>4 Q. So you can't tell me without reading the</p> <p>5 report?</p> <p>6 A. My opinions are stated in my report. I'm</p> <p>7 not going to create new opinions as we sit here today.</p> <p>8 I'd be glad to review any opinion in here and have you</p> <p>9 ask me questions about the specific statements in my</p> <p>10 report.</p> <p>11 Q. So you're incapable of telling the jury</p> <p>12 what your opinions are without reading them off your</p> <p>13 report?</p> <p>14 MS. BROOKER: Objection, form.</p> <p>15 A. I'm not willing to formulate new opinion as</p> <p>16 we sit here. I'm quite capable of telling the jury my</p> <p>17 opinions that I've taken great time and care to craft</p> <p>18 based on evidence and information in the case and to</p> <p>19 document in a hundred page report. And I spent time</p> <p>20 to include all of the things that I felt were relevant</p> <p>21 to what I was asked to do and documented them in here.</p> <p>22 And I'm quite capable of addressing that with the jury</p>
<p style="text-align: right;">Page 624</p> <p>1 A. That's not what I said. I said I won't</p> <p>2 form a new opinion. I would be glad to read or rely</p> <p>3 upon or say that the opinions stated in this report</p> <p>4 are my opinion with respect to Dey and the WACs it set</p> <p>5 and the degree to which it related to their actual</p> <p>6 acquisition price.</p> <p>7 Q. Well, what is your opinion of the Dey WAC</p> <p>8 and how it related to its acquisition price?</p> <p>9 MS. BROOKER: Objection, form.</p> <p>10 A. I don't see that I have a statement that</p> <p>11 addresses that specifically. There are many</p> <p>12 statements that --</p> <p>13 Q. Did Dey --</p> <p>14 MR. BREEN: Whoa. Counsel, please stop</p> <p>15 interrupting the witness.</p> <p>16 A. There are many statements that do talk</p> <p>17 about Dey AWP's in relation to the actual acquisition</p> <p>18 cost or in relationship to a spread that I think</p> <p>19 address a similar issue. And there are many</p> <p>20 statements in here about that.</p> <p>21 Q. Did Roxane in your opinion inflate its</p> <p>22 WACs?</p>	<p style="text-align: right;">Page 626</p> <p>1 and I would be happy to do so.</p> <p>2 But I'm not going to sit here and formulate</p> <p>3 new opinions with one-off quick questions from you</p> <p>4 that aren't directly tied to opinions I've put forward</p> <p>5 in my report.</p> <p>6 Q. Did Dey inflate its AWP for its albuterol,</p> <p>7 cromolyn or ipratropium products? Did you form an</p> <p>8 opinion on that one way or the other?</p> <p>9 A. If you will permit me a minute I'll find a</p> <p>10 few things in the report that do relate to that.</p> <p>11 There was -- related to cromolyn, Dey</p> <p>12 marketed cromolyn and then it was noted in a document</p> <p>13 that Dey did increase the reimbursement spread for</p> <p>14 cromolyn. There was a memo regarding cromolyn sales</p> <p>15 update that was provided by Mr. Robert Mozak to</p> <p>16 Charles Rice, the CEO of Dey.</p> <p>17 And in that memo Mr. Mozak says, and I</p> <p>18 quote "'After five months of marketing of cromolyn,</p> <p>19 marketing has conducted extensive analyses to</p> <p>20 determine the sales status of cromolyn to date.' In</p> <p>21 response to that analysis program adjustments were</p> <p>22 recommended, including 'Price modifications have been</p>

64 (Pages 623 to 626)

Schondelmeyer, Pharm.D., Ph.D., Stephen W. - Vol. II

February 26, 2009

Washington, DC

<p style="text-align: right;">Page 631</p> <p>1 I think Medicaid expects that the companies would 2 report those discounts so that Medicaid can take those 3 into account in their payment policy. 4 Q. Now, in your report did you see any 5 evidence of Dey discussing the spread with customers? 6 A. Again, I'd have to look back through my 7 statements and see that. I'd have to look back and 8 see. 9 Q. So without reading the whole report you 10 can't answer that question? 11 A. I'd need to reread the statements I made 12 with respect to Dey and their conduct in terms of 13 pricing. Again, I didn't commit that to memory. 14 Q. By the way, am I correct that the portion 15 of your report dealing with Dey is -- where is that? 16 A. Well, the primary portion is in -- like 17 page 51 to 57. 18 Q. So it's six pages on Dey that you're having 19 trouble recalling? 20 A. Six pages specifically on Dey, yes. 21 Q. Let's go to the end of your report. Okay. 22 Paragraph 212. Do you see there it says "Roxane and</p>	<p style="text-align: right;">Page 633</p> <p>1 price was inflated? 2 A. It's my intention to convey exactly what 3 the sentence says, that Roxane and Dey reported prices 4 to their commercial drug price database that were 5 inflated in relation to the actual drug prices. The 6 ones that were reported were inflated in relation to 7 actual drug price. 8 Q. Which Dey and Roxane WACs were inflated? 9 Which products? 10 A. Well, again, that's stated in my reports 11 where I discuss the specific conduct of Dey and the 12 section where I discuss the specific conduct -- 13 Q. Point it out to me. 14 A. -- of Roxane. 15 Q. I don't see it. Point it out. 16 A. Well, first of all we need to clarify this 17 states "inflated in relation to actual drug prices." 18 And that can occur by moving the WAC or AWP up. Or 19 inflation can also occur by lowering the actual price 20 and keeping the AWP or WAC at the same level. Either 21 of those would be inflated by my definition and by the 22 meaning of my statement here.</p>
<p style="text-align: right;">Page 632</p> <p>1 Dey reported prices to the commercial drug price 2 databases that were inflated in relation to actual 3 drug prices?" 4 A. I see that statement, yes. 5 Q. Do you see that? What evidence do you have 6 in this report that Dey's WAC was inflated in relation 7 to actual drug prices? 8 MR. BREEN: Objection, form. 9 Q. Point it out to me. 10 A. Well, first of all, this conclusory 11 statement doesn't necessarily say WAC. It says that 12 "Reported prices to commercial drug price databases 13 were inflated in relation to actual drug prices." 14 So -- 15 Q. So you're not intending to encompass WAC in 16 that statement? 17 A. WAC to the degree that they were reported 18 could be encompassed there and AWP to the degree that 19 it was reported is encompassed there. 20 Q. I'm not asking you could be. You're the 21 guy who report the report. Was it your intention to 22 convey to the reader in that report that Dey's WAC</p>	<p style="text-align: right;">Page 634</p> <p>1 Q. Show me the evidence in your report that 2 shows that Dey's WACs were inflated? 3 A. Well, among others was the statement that I 4 pointed out to you just a few minutes ago. 5 Q. Oh, really? 6 A. Again, you're saying WACs. I'm talking 7 about both prices that were reported, which could be 8 AWP or WAC. 9 Q. You have to answer the question that's 10 asked. My question is limited to WACs. 11 A. I'd have to go back and look at the data 12 that I used to formulate my analysis and report and I 13 don't have that in front of me right now. I would 14 have to go back and look at that to answer that 15 question. 16 Q. So sitting here under oath -- 17 A. I believe these statements in here to be 18 truthful and based on analysis and reviewing documents 19 in this case. 20 Q. Well, nevertheless, sitting here today 21 after preparing for the past week you cannot point out 22 any evidence to me that supports a claim that Dey's</p>

66 (Pages 631 to 634)